User Manual

Deltec Cozmo™ Insulin Pump

Deltec Cozmo™

The Freedom to Be You.™

Congratulations! You have selected the **Deltec Cozmo™ Insulin Pump** to help you in the treatment of your diabetes.

This manual provides information on programming, using and maintaining your Deltec Cozmo™ Insulin Pump. It is very important that you read the manual carefully, and ask questions if there is something you don't understand. Keep this manual handy and become thoroughly familiar and comfortable with the use of your pump.

The issue date of this manual is included on the back cover. If your manual is a year or more old, contact Deltec, Inc. (or check the web site at www.DeltecCozmo.com) to see if a newer manual is available.

If you have comments, questions, or problems...

If you have comments or questions about the pump, please call the appropriate number given at the right side of this page. You will be asked for the pump's serial number, which you will find on the back of the pump.

If you have questions about your insulin therapy or your health, contact your healthcare provider.

Our staff at Deltec is available to help you 24-hours a day with the programming and operation of your pump.

U.S. Distribution

ATTENTION: Deltec, Inc.
3183 Riverport Tech Center
Maryland Heights, MO 63043 USA
www.DeltecCozmo.com
Customer Service (USA, Canada): 1-800-826-9703
Fax: 1-800-209-2145

European Representative

Graseby Medical Ltd.
WD24 4LG UK
+44 (0)1923 246434

Table of Contents

Important Information

Important safety information 1
- Warnings 1
- Cautions 4

Explanation of symbols 6
Introduction 7
- Indications 7
- Contraindications 7
- Delivery features 7
  - Basal rates 7
  - Meal bolus 8
  - Correction bolus 8
- Other features 8

Glossary of terms 9
Pediatric use 13
About this manual 14

About the Pump

Pump illustrations 15
Description of features and buttons 16
- Battery compartment 16
- Display 16
- Programming keys 16
- Up and down keys (▲ / ▼) 16
- Touch bolus button 16
- Cartridge cap 16
- Infrared (IR) windows 16
- Features 17
  - Vibration alert 17
  - Occlusion (blockage) sensor 17
  - Cartridge sensor 17
  - Watertight 17
  - History 17

Description of pump display & menus 18
Deltec accessories 20
- Cartridge 20
- Infusion sets 20
- Infrared (IR) adapter 20

Before using the pump for the first time 21
- Insert a battery 21
- Self tests 22
- Attach the belt clip (Optional) 23

Pump settings 24
- Regional settings 24
- Time and date 26
- Beep or Vibrate 27
- Personalizing alerts 28

Suspending and restarting insulin delivery 31
Program Lock 32
- Unlocking the menu 33

Notes 34

Using the Pump - Basics

Loading a cartridge 35
- Supplies required 35
- 1. Filling the cartridge 35

2. Attaching an infusion set and loading a filled cartridge into the pump 36
3. Fill the tubing 40
4. Choosing an access site and inserting the access device 41
5. Fill the cannula 42
6. Set site change reminder and restart delivery 43
Meal Bolus 44
Standard bolus (units of insulin): setup 45
Standard bolus: delivery 46
Carbohydrate bolus: setup 47
Carbohydrate bolus: delivery 48
Basal patterns 49
Personalizing basal patterns 50
Editing basal patterns 51
Using basal patterns 53
Notes 54

Help

About the alarms (Beep/Vibrate settings) 55
Troubleshooting 56
Alarms 56
Alerts 58
Other messages 62
Cleaning your pump 65
Servicing your pump 66
Troubleshooting health problems 67
Low blood glucose (hypoglycemia) 67
High blood glucose (hyperglycemia) 68
Diabetic Ketoacidosis (DKA) 70
My DKA plan 70
Skin infections 71
Tips for sick days 71
My sick day plan 72
Emergency supplies 72
Personal pump removal guidelines 73
Your pump &:
Extreme temperatures 73
Water 73
Contact Sports 74
Your basal rates, boluses &
Your weight 74
Your level of exercise 74
Your growth (children & teens) 74
Your menstrual period 74
Starting new medications / supplements 74
If you drop your pump or hit it hard 75
Notes 76

Using the Pump - More Features

Programming and using these features 77
Correction Bolus 77
Personalizing the correction bolus 79
Delivering a correction bolus (main menu) 80
Touch Bolus 81
Making Touch Bolus available 82
Delivering a Touch Bolus 83
Extended Bolus 85
Personalizing the extended bolus 86
Delivering an extended bolus 87

Stopping an extended bolus 88
Combination Bolus 89
Personalizing the combination bolus 90
Delivering a combination bolus 91
Stopping a combination bolus 92
Temporary Rate 93
Personalizing the temporary rate 94
Using the temporary rate 95
Stopping a temporary rate 96
Notes 97

History & Communications

History 99
Personalizing history 100
Viewing history on the pump 101
Communications 102
My Treatment Assistant™ PC Communications System .. 102
Notes 104

Technical Information

Pump development standards 105
Specifications 106
General specifications (nominal) 106
Delivery specifications 108
Main Menu 108
Meal Bolus 108
Correction Bolus 109
Temporary Rate 110
Basal Pattern 111
Load Cartridge 111
History 111
Pump Settings 112
Pump Settings / Personalize / Alerts 112
Regional Settings 113
Personalization using My Treatment Assistant™ 113
Accuracy test results 114
Trumpet curves 114
Safety features and fault detection 116
Hardware safety features 116
Watchdog timer circuit 116
Motor drive / motor watchdog circuit 116
Voltage detection circuit 117
Software safety features 117
Hardware-related software safety features 117
RAM memory check 117
Motor circuit check 118
Keypad encoder check 118
Data handling and software safety features 118
Data stored in RAM 118
Data stored in NOVRAM 118
Data used in calculations 119
Timer data registers 119
Inspecting the pump 119

Index 120

Limited Warranty 123

What's In This Section?

Important Safety Information
- Warnings and Cautions

Explanation of symbols
Introduction
Glossary of terms
Pediatric use
About this manual

Important safety information

WARNING: Read this entire manual before using the Deltec Cozmo™ Insulin Pump. If you do not understand something or have any questions, ask your healthcare provider, or contact Deltec, Inc. Incorrect use of this pump, failure to follow the instructions and important information contained in this manual, or improper/inadequate troubleshooting can lead to death or serious injury. Warnings, cautions and other important safety information can be found in this section, and in bullet form throughout the manual (indicated by the ☞ symbol). The Help section (chapter 4, page 55) contains information on troubleshooting pump and health related problems, as well as other important information.

WARNINGS

- ☞ **The Deltec Cozmo™ Insulin Pump is designed only for Continuous Subcutaneous Insulin Infusion (CSII). Do not use this pump for any other type of therapy.** It is not for use with blood or cellular blood products. Use the pump only as you have been trained, and as instructed in this manual.
- ☞ **This manual describes how to use and troubleshoot the Deltec Cozmo™ Insulin Pump. Deltec does not, however, make any recommendations about any specific programming related to your diabetes therapy.** You must work closely with your healthcare provider in programming the pump, and in determining whether certain features are appropriate for you. Before using the pump, you must receive appropriate training in all it's functions and in troubleshooting problems. Regular medical checkups are required while you are using the Deltec Cozmo™ Insulin Pump for insulin therapy.
- ☞ **Monitor your blood glucose levels regularly** (*at least* 4 to 6 times per day, or as your healthcare provider recommends) so that high or low blood glucose levels can be identified quickly.
- ☞ **Deltec, Inc. recommends that you have someone around you (family, friends, etc.) that understands diabetes and pump therapy, and can help you in the event of an emergency.** Make sure they are familiar with any information given to you by your healthcare provider.
- ☞ **If pump operation is interrupted for any reason, you must be prepared to inject insulin.** Since the pump uses only short-acting U100 insulin, high blood glucose (hyperglycemia) can quickly (2 to 4 hours) develop into Diabetic Ketoacidosis (DKA).
- ☞ **To avoid a risk of explosion**, do not use the pump in the presence of flammable anesthetics or explosive gases.
- ☞ The Deltec Cozmo™ Insulin Pump and accessories include small component pieces that **could pose a choking hazard to small children.**
- ☞ Several hours before going to bed, **make sure the cartridge contains enough insulin to last through the night.** Do not use the "vibrate" alarm at night. If you are a very deep sleeper, you may want to set the audio volume to High (the loudest setting) before going to bed.

- **Make sure that all caregivers, including for instance school personnel, daycare providers, etc., are familiar with the features of the pump, and can use and troubleshoot the pump.** Make sure they are familiar with any information given to you by your healthcare provider.
- Deltec infusion sets are recommended for use with this pump. **Pump operation and accuracy may not be assured if you use other manufacturers' products.**
- **If there are any system problems, the pump will stop the tests and display an alarm screen letting you know there is a problem. If this happens, do not use the pump.**
- **The time and date must be set correctly, since basal patterns are time-based, and all of the history is stored based on time and date.** Occasionally you will need to reset the time, for example, during daylight savings time or to adjust for a different time zone.
- When stopping delivery, remember that since the pump uses only short-acting insulin, your insulin level will start to fall and blood glucose level to rise very quickly (in as little as 90 minutes). **You must test your blood glucose when stopping delivery for any length of time.**
- Once the pump is locked, you will not be able to enter the menu without the proper code. Touch Bolus is also not allowed when the pump is locked. Make sure there is someone around who knows the proper code.
- **Always use the pump's Load feature when starting a new cartridge.** This will assure that the cartridge is properly loaded and the tubing and access device are filled with insulin.
- **Whenever you load a new cartridge and attach an infusion set, you must test your BG level within 1 to 2 hours to make sure that insulin is being properly delivered.** If you do not test within this time-frame, and insulin delivery is delayed or blocked, you may develop hyperglycemia. If desired, you can use the Glucose Reminder alert to remind you to test your BG level (see Personalizing Alerts, page 28).
- **Always use "aseptic" technique, particularly when working with the cartridge, infusion set, catheter and access site**. An increased risk of skin infection is associated with pump use, as the access device remains in place for 2 or more days (see "Aseptic Technique," page 9).
- **Always read the instructions for use** provided with the insulin, catheter, infusion set, and any other accessory used with the Deltec Cozmo™ Insulin Pump.
- **To avoid accidentally infusing insulin, disconnect the infusion set tubing from the access device (or site) before removing a used cartridge or replacing an infusion set.** Never use the pump's "load cartridge" or "fill tubing" features while an infusion set is connected to your body. You could deliver an unintended dose of insulin, resulting in low blood glucose (hypoglycemia).
- **If not properly tightened, insulin could leak from the cartridge and infusion set connections and disrupt delivery** (the insulin that leaks out is not being delivered into your body like it should be and, depending on how much insulin is leaking, could cause your BG level to rise). Signs

of leakage can also mean opportunity for contamination leading to infection.

- ☞ **Never use Fill tubing when the infusion set is connected to your body**, or you could deliver an unintended bolus.
- ☞ **Always remove all air from the cartridge and infusion set before starting insulin delivery. Air bubbles in the system can slow or stop insulin delivery.** Check all connections carefully for leaks (wrapping a tissue around connections to check for moisture is a good technique), as leakage can slow or stop insulin delivery to the body, and allow an opening for contamination leading to infection. If insulin delivery is slowed or stopped, high blood glucose (hyperglycemia) will result.
- ☞ **You should not change your access site right before bed, as you would be unaware of any problems with the site.** You must test your BG level 1 to 2 hours after starting a new cartridge to make sure insulin is being properly delivered.
- ☞ **You should receive specific training on programming and delivering a meal bolus and using basal patterns.** Please carefully read all instructions and talk to your healthcare provider.
- ☞ **It is vital to get the basal patterns correct.** If a basal rate is too high or too low, all your insulin delivery throughout the day and night will be incorrect, including boluses.
- ☞ **Many things can affect how your body uses insulin. To avoid problems, contact your healthcare provider before making big lifestyle changes**, such as starting or stopping an intensive exercise program, or if you experience a significant weight loss or weight gain, etc. In these cases your basal rates may need to be modified.
- ☞ **When returning a pump for service, you must be prepared to inject insulin with an insulin syringe or pen until the new pump arrives.** Contact your physician if you require supplies, such as a prescription for intermediate- or long-acting insulin and syringes.
- ☞ **You must not use the replacement pump until it is correctly personalized.**
- ☞ **Never stop taking your insulin because of illness.** Even if you are too sick to eat, your body still needs insulin.
- ☞ **During an illness, check your BG level before mealtime and every 2 to 4 hours. Check your urine for ketones until you feel better.**
- ☞ **Even though you are sick, you still need fluids, calories and carbohydrates.** Drink 4 to 8 ounces of clear liquids containing sugar every 30 to 60 minutes.
- ☞ **If you drop the pump or hit it against something hard, always inspect it carefully to make sure it is still working properly.** Make sure the display is working correctly, and the cartridge, cartridge cap, battery cap and infusion set are connected correctly. Wrap a piece of tissue paper around the connections to check for moisture (which could indicate a leak). If there is damage to the pump outer shell (cracks, chips), the pump may no longer be watertight.
- ☞ **If the display has missing or incomplete characters, or if the pump does not seem to be working correctly, stop using the pump immediately.** Contact your healthcare pro-

vider for health advice and Deltec, Inc. for information on servicing your pump. Be prepared to inject insulin with an insulin syringe or pen.

- ☞ **Programming and using the features described in the "Using the Pump - More Features" chapter includes information that may require a greater understanding of insulin pump therapy and should not be attempted without help from your healthcare provider.**
- ☞ Programming many of the settings in the "Using the Pump - More Features" chapter can only occur after testing and fine-tuning so that you get the best possible results from insulin pump therapy. **You should receive specific training on programming and using the pump. Please carefully read all instructions and talk to your healthcare provider.**
- ☞ **Talk to your healthcare provider to determine your correction bolus factor and your duration of insulin action.**
- ☞ **When you first start using the Touch Bolus feature, you should always take the pump out so you can view the screens as you program them.** Then, once you are comfortable with how it works, you can program and deliver a bolus without even taking the pump out.
- ☞ **To use the Extended bolus feature, you will need to determine the length of time it takes your body to begin using these types of meals as blood glucose.** Talk to your healthcare provider before attempting to use this feature.
- ☞ **To use the Combination bolus feature, you will need to determine the length of time it takes your body to begin using these types of meals as blood glucose.** Talk to your healthcare provider before attempting to use this feature.
- ☞ **Discuss your individual insulin needs with your healthcare provider.**

Cautions

- ☞ **Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI) and direct x-ray, as they can affect how the pump works.** If you cannot avoid them, you must take the pump off. Do not expose the pump directly to ultrasound.
- ☞ **Do not use the pump in hyperbaric chambers** as they will affect how the pump works and may also cause damage to the pump.
- ☞ **Do not use cell phones in close proximity to the pump.** Interference with the pump electronics by cell phones can occur. If a cell phone interferes with the pump, the pump will generate a System Fault alarm.
- ☞ To avoid damage when storing the pump, first remove the battery and cartridge. Place the pump in the original carton and keep it away from cold, heat, and dampness. After 30 days, your personal programming will be lost and you will need to reprogram your pump.
- ☞ The pump may experience problems if operated in conditions where temperatures are lower than 35.6˚F (2˚C) or higher than 104˚F (40˚C), when relative humidity (non-condensing) exceeds 90%, and when atmospheric pressure is lower than 10.2 PSI (70 kPa) (10,000 feet above sea level) or higher than 15.4 PSI (106 kPa). If you experience prob-

lems, remove the pump from use.

- ☞ The pump may be damaged if stored in environments where temperatures are lower than –4˚F (–20˚C) or higher than 140˚F (60˚C), when relative humidity (non-condensing) exceeds 90%, and when atmospheric pressure is lower than 10.2 PSI (70 kPa) (10,000 feet above sea level) or higher than 15.4 PSI (106 kPa).
- ☞ **Do not use NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries.** They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.
- ☞ **Use only Deltec Cozmo™ 3mL Insulin Cartridges**; other manufacturers' products will not work with the Deltec pump.
- ☞ **Strong household cleaners and chemicals will damage the pump's outer shell** if applied directly or indirectly (on your hands, for instance). Avoid the following in particular:
  - Household cleaners (such as Formula 409®)
  - Jewelry cleaner
  - Petroleum-based products (such as gasoline or GooGone®)
  - Products that contain high levels of D.E.E.T. (such as Deepwoods Off® insect repellent)
- ☞ **Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your pump, as they can scratch, discolor or damage the pump's outer shell.** If the display is scratched, it may be difficult to read and you will need to have it replaced. If the outer shell is chipped or cracked, it will no longer be watertight and will require service.
- ☞ **Never use steam or very hot water (exceeding 120˚F [49˚C]) in an attempt to sterilize the pump. Never put your pump in the dishwasher.** Exposing the pump to these high temperatures could damage the pump's electronics and result in the need to service your pump.

Explanation of symbols

Below is a list of symbols you will see on (or on the packaging of) the Deltec Cozmo™ Insulin Pump and accessories, as well as explanations of what the symbols mean.

SN Serial number

Attention! See instructions for use

Type CF equipment (protection from electric shock)

IPX8 Watertight when submerged to 8 feet (2.4 meters) for 30 minutes or to 12 feet (3.6 meters) for 3 minutes

Date of manufacture

On Product Packaging: Use by

On Pump Display: Wait

Rx ONLY CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician

REF Reorder number

CE 0473 or CE Indicates that the product was designed and manufactured in accordance with applicable standards/guidelines and may be sold in the EU (European Union)

Appears in pump display, with a message, to indicate a question you must answer before programming can continue

Appears in pump display, along with a message, as an indicator of an alarm condition.

Dispose of used batteries in an environmentally safe manner, and according to any regulations that may apply

Latex free

Press ▲ or ▼ keys to move through menu/settings

Top of menu; press ▲ key to move through menu

Bottom of menu; press ▼ key to move through menu

Press Touch Bolus button

Approximate insulin left in cartridge

Approximate battery life remaining

Home screen page number

Meal Bolus (menu)

Correction Bolus (menu)

Temporary Rate (menu)

Basal Pattern (menu)

Load (menu)

History (menu)

Pump Settings (menu)

Keep dry

Handle with care

Keep from direct sunlight

Storage temperature range

Important safety information, warnings and cautions

Introduction

Congratulations! You have selected the **Deltec Cozmo™ Insulin Pump** to help you in the treatment of your diabetes.

Indications

The Deltec Cozmo™ Insulin Pump is a syringe infusion pump designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes.

Contraindications

The pump is not indicated for anyone who cannot or will not test blood glucose levels at least 4 times per day, as well as maintaining regular contact with their diabetes team.

Delivery features

The pump is used to deliver insulin in two ways, as basal insulin and as bolus insulin.

Basal rates

The pump is programmed to deliver a steady background flow of insulin called the "**basal rate**." You can program up to 4 separate basal rate patterns. Each pattern can contain up to 48 time/rate segments to meet your insulin needs throughout the day and night.

- You decide which patterns to display in the menu, and also choose a name for each pattern from a predetermined list. Or, you can use My Treatment Assistant™ PC Communica-

tion System to create a name for each pattern.

- The pump also offers a "**Temporary Rate**" feature which allows you to program a temporary basal rate on the pump.

Meal bolus

The pump is programmed to deliver a "**bolus**" of insulin to match food eaten.

- You decide how you want to program a meal bolus, either by entering the number of units of insulin you want delivered, or by entering the amount of carbohydrate in your meal/snack for the pump to calculate and recommend how much insulin is needed to cover the meal/snack.
- The pump also has an "**Extended bolus**" and a "**Combination bolus**" feature. The extended bolus is delivered over a longer period of time (which you specify), and may be used for high fat or protein meals, or if you have gastroparesis. The combination bolus delivers a percentage of the bolus (which you specify) right away, then the rest is delivered over a longer period like the extended bolus. If you choose not to use these features, you can program the pump so that they are not displayed in the menu.
- The pump has an alternate, discrete method of delivering a meal bolus, called the "**Touch Bolus**," which is initiated by pressing the Touch Bolus button on the side of the pump. This feature can also be turned off if you choose not to use it.

Correction bolus

- The correction bolus is used to lower high Blood Glucose (BG) levels. A correction bolus can be displayed in the main menu, as part of the meal bolus, both, or neither if you choose not to use the feature. It can be programmed in either mg/dl or mmol/L, whichever you use when testing your BG levels.

Other features

The pump has a large display (or screen) where all programming, operating and alarm information is displayed. Programming of the pump is menu-driven, like an ATM or cell phone.

The pump is powered by one "AAA" (IEC LR03) alkaline battery, which is readily available at most grocery stores, hardware stores, drug stores, electronic stores, and any other stores that sell AAA replacement batteries. Average battery life (depending on how your pump is programmed and used) is approximately 1 month.

☞ **Caution: Do not use NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries.** They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

The pump is watertight, so you do not have to remove the pump when showering or bathing, and allows unlimited swimming activities. When diving, the pump is watertight to a depth

of 8 feet (2.4 meters) for 30 minutes or 12 feet (3.6 meters) for 3 minutes.

Pump and delivery history is automatically tracked by the pump, and can be viewed in the **History** menu (see page 99 in chapter 6 of this manual for a list of available history).

The pump has a Program Lock feature which allows you to lock out the menu. This feature helps prevent tampering with the pump.

The pump requires the use of the Deltec Cozmo™ 3mL Insulin Cartridge and one of the Deltec Insulin Infusion Sets.

Glossary of Terms

The following is a list of terms that you should know before reading this manual, because the manual uses these terms often:

Access site: The area on the body into which the cannula or needle of the infusion set is inserted.

Aseptic technique: Aseptic technique is used to minimize the risk of infection. Use aseptic technique when working with the cartridge, infusion set, cannula/needle and preparing the access site. Wash your hands thoroughly with soap and water. Do not touch or blow directly on any part that comes in contact with insulin (the "fluid path"). Make sure the area (counter or tabletop, etc.) where you are working is clean.

BG level: See *Blood Glucose Level*.

Basal Pattern: A 24 hour sequence of basal rates.

Basal rate: The amount of insulin delivered continuously over 24 hours a day, providing a background of insulin at all times. The user programs the basal rate to deliver insulin continuously. The rate programmed is intended to keep the blood glucose within the user's target range between meals and overnight. The basal rate is measured in ***units per hour*** (u/hr).

Blood Glucose level (BG level): The amount of glucose in the blood. BG levels average 100 mg/dl (5.5 mmol/L) for someone without diabetes. Your healthcare provider will help you

determine a "target range" for your blood glucose level.

Bolus: An insulin dose given at the time of a meal to match the glucose from food eaten or to lower the blood glucose level when it's higher than the target range.

Cannula: A small, soft tube, inserted into the body, through which insulin is delivered.

Cartridge: The container that holds the insulin. The Deltec Cozmo™ 3mL Insulin Cartridge looks like a small syringe.

Combination Bolus: The combination bolus combines the features of a regular meal bolus with an extended bolus. Part of the bolus (which you specify) is delivered immediately, then the rest of the bolus is delivered over an extended period (which you also specify). The combination bolus can be used when eating a meal that contains both rapidly and slowly absorbed carbohydrates, such as pizza.

Correction Bolus: An insulin dose given to lower the blood glucose level when it's higher than the target range.

Correction bolus factor: This is a mathematical formula used to calculate the amount of insulin you need to correct or lower a high blood glucose. The formula takes into account your current blood glucose, your target blood glucose, the amount 1 unit of insulin will lower your blood glucose and your duration of insulin action. The calculation will recommend the amount of insulin you need to lower your blood glucose to target.

CSII: Continuous Subcutaneous Insulin Infusion.

DKA: *See Diabetic Ketoacidosis.*

Dawn phenomenon: A rise in the early morning blood glucose level due to the activity of hormones in the body.

Diabetes: A disease resulting in the body not being able to produce or properly use insulin. In Type 1 diabetes, the body no longer **produces** insulin. In Type 2 diabetes, the body loses the ability to properly **use** insulin.

Diabetes team: You are the captain of the team that includes one or more of the following: your doctor, nurse educator, nutritionist and support team.

Diabetic ketoacidosis (DKA): A serious condition that occurs when there is not enough insulin to allow the glucose in the blood to be used by the cells in your body for energy. The cells begin to burn the body's stored fat reserves for fuel. Ketones are produced when fat is burned and these ketones change the chemistry of the body. Ketones can be detected using a blood or urine test. DKA can happen within a few hours when there is not enough insulin available, and can lead to unconsciousness and death.

Duration of insulin action: A certain amount of time insulin is active and available in the body after it has been given by a subcutaneous bolus. Talk with your healthcare provider to help you determine your duration of insulin action through blood glucose testing.

Extended bolus: A meal bolus delivered over an extended period of time. The extended bolus can be used when you eat a high fat or high protein meal, if you're eating over an extended period of time (such as a banquet), or if you have gastroparesis.

Factor: One of two or more values used in a mathematical formula. The pump uses certain "factors" when making calculations, for instance the correction bolus factor.

Fluid path: The areas inside the cartridge and infusion set that come into direct contact with the insulin. These areas include the inside of the tubing and connectors, the inside and tip of the needle and cannula, and the inside and tip of the cartridge. To help protect against infection, never touch or blow directly on any part of the fluid path.

Gastroparesis: A diabetes complication resulting in the slowing of food digestion.

Gestational diabetes: A form of diabetes that develops in women during pregnancy.

Glucose: The main source of fuel for the body. Foods containing carbohydrate are the main source of glucose in the body, although foods containing protein also provide some glucose. Foods containing fat also have an effect on blood glucose.

High blood glucose (hyperglycemia): Blood glucose level higher than target. Signs and symptoms include: increased thirst, frequent urination, blurred vision and high BG reading upon testing.

Increment: An added (or subtracted) amount. On the pump, you personalize how you want the pump to increment bolus amounts (carbohydrate increments of 1, 2, 3, 4, 5, 10 or 15 grams; units of insulin by 0.05, 0.10, 0.50, or 1.00 units). Then when you program a bolus, the pump counts up or down using the increment you have chosen.

Infusion set: The tubing that is attached to the end of the cartridge, through which the insulin is delivered into the body.

Insulin pump: A small electromechanical medical device designed specifically for delivering precise amounts of insulin into the body in the treatment of diabetes. The Deltec Cozmo™ Insulin Pump systems are controlled by 2 microprocessors (computer chips) which continuously monitor each other to make sure the systems are working properly.

Insulin to carb ratio: The number of grams of carbohydrate covered by each unit of insulin delivered. Your healthcare provider will help you determine your insulin to carb ratio.

Ketones: A substance in the blood resulting in a change in the acid base balance of the blood. Ketones can be tested in the blood and urine.

Low blood glucose (hypoglycemia): Blood glucose level lower than target. Signs and symptoms may include: shakiness,

sweating, dizziness, cold or clammy skin, looking pale, tingling and numbness in hands or around lips, mood changes. Low blood glucose may lead to loss of consciousness.

mg/dl: Milligrams per deciliter. In the USA, your BG level is typically measured in mg/dl.

mmol/L: Millimoles per liter. mmol/L is the international (except in the USA) standard for measuring BG levels.

My Treatment Assistant™ PC Communication System: A (Microsoft® Windows®-based) computer program designed for use with the Deltec Cozmo™ Insulin Pump. Through My Treatment Assistant™, you can perform pump programming, print or e-mail history reports and pump settings, and save pump and delivery history.

Occlusion: Clog or blockage. Occlusions are associated with the infusion set and access site, and mean that insulin delivery is stopped. Blockage can be caused by a number of things, including the tubing being pinched or kinked, the cannula or needle being blocked, as well as other reasons.

Pushrod: On the Deltec Cozmo™ Insulin Pump, the cartridge is attached to the pushrod and, when the pump is started, the motor causes the pushrod to move forward and push insulin through the infusion set into your body.

Subcutaneous: The area of the body directly below the skin but above the muscle. The infusion set cannula or needle is inserted subcutaneously.

Temporary Rate: A feature on the pump which allows you to temporarily increase or decrease the basal rate.

Type 1 diabetes: Type 1 diabetes refers to the condition where specialized "beta" cells in the pancreas are destroyed, and the body is unable to produce insulin.

Type 2 diabetes: Type 2 diabetes refers to the condition where the body, while it is still able to **produce** insulin, loses its ability to **use** that insulin.

Pediatric use

Use of an insulin pump by pediatric patients should always be under the instructions of a physician, and requires supervision by a parent or a designated caregiver. The Deltec Cozmo™ Insulin Pump has many safety features that are designed with pediatric use in mind, and are described in this manual and summarized below:

- Program Lockout: prevents user (or anyone else) from entering the pump menu to prevent changing pump programs. When program lockout is in use, to enter the menu you must use the code. Program lockout cannot be turned on or off unless you know the code.
- A display in the home screen can be programmed using My Treatment Assistant™ PC Communications System to display emergency phone numbers to call should a problem arise.
- A number of alerts and reminders specifically address pediatric use:
  - Missed meal bolus alert – pump alerts if a meal bolus is not given during time periods that are programmed into the pump.
  - Delivery limit alarm – programed to limit the amount of insulin that can be delivered over an hour.
  - Low cartridge volume alert – can be programmed to alert at selectable levels of insulin remaining in the cartridge.
  - Infusion set change reminder – alert that can be programmed to change infusion set and access site after selectable time period.
- Delivery limits:
  - Maximum Bolus – programmed to limit the amount of insulin delivered in a bolus.
  - Maximum basal rate – programmed to limit the maximum programmable basal rate
- Other features:
  - Basal rates can be programmed to 0.05 u/hr. Also, you can program and deliver a bolus in 0.05 units of insulin increment. These features provide more flexibility and safety for younger pediatric patients.
  - Parents or caregivers can easily recall pump delivery history to view all delivery events.
  - The pump can be programmed with different insulin to carbohydrate ratios and labeled for different meals - breakfast, lunch, dinner, snack.
  - Amount of meal bolus can be programmed in units of insulin or grams of carbohydrate. If using grams of car-

bohydrate, the user's insulin to carbohydrate ratio is programmed into the pump and used to calculate the amount of insulin needed for a specified amount of carbohydrates, avoiding the paper and pencil calculations that are currently used.

All of these features are described in detail in the manual. They can be activated at the physician, parent or caregivers discretion through the easy to use "menu" based personalization features of the pump or by using My Treatment Assistant™ PC Communications System.

☞ **Warning: Make sure that all caregivers, including for instance school personnel, daycare providers, etc., are familiar with the features of the pump, and can use and troubleshoot the pump.** Make sure they are familiar with any information given to you by your healthcare provider.

About this manual

The first part of this manual (**Important Information**, **About the Pump**, **Using the Pump - Basics** and **Help**) includes information on the basic operation and troubleshooting of the pump. This includes inserting batteries, setting the time and date, programming and using basal patterns, programming and delivering a meal bolus, and loading an insulin cartridge into the pump. For many pump users, these chapters contain the information you will primarily be concerned with during your basic training, and until you are more comfortable with your pump and have received appropriate training on the other features.

The second part of the manual (**Using the Pump - More Features**, **History & Communications**) contains information on programming and using the pump's other features. In order to program and use many of these features, a greater understanding of diabetes therapy is required.

Technical Information contains pump specifications and descriptions of the pump's internal safety systems. You do not need to be familiar with this information to use the pump.

Throughout the manual are areas for writing notes, as well as for writing therapy information specific to you.

What's In This Section?

The Freedom to Be You.™

- Pump Illustrations
- Description of features and buttons
- Description of pump display and menus
- Deltec Accessories
- Before using the pump for the first time
  - Insert a battery
  - Self tests
  - Attach the belt clip (optional)
- Pump Settings
  - Regional Settings
  - Time and date
  - Beep or vibrate
  - Personalizing alerts
- Suspending and restarting delivery
- Program lockout

Pump illustrations

Figure 1

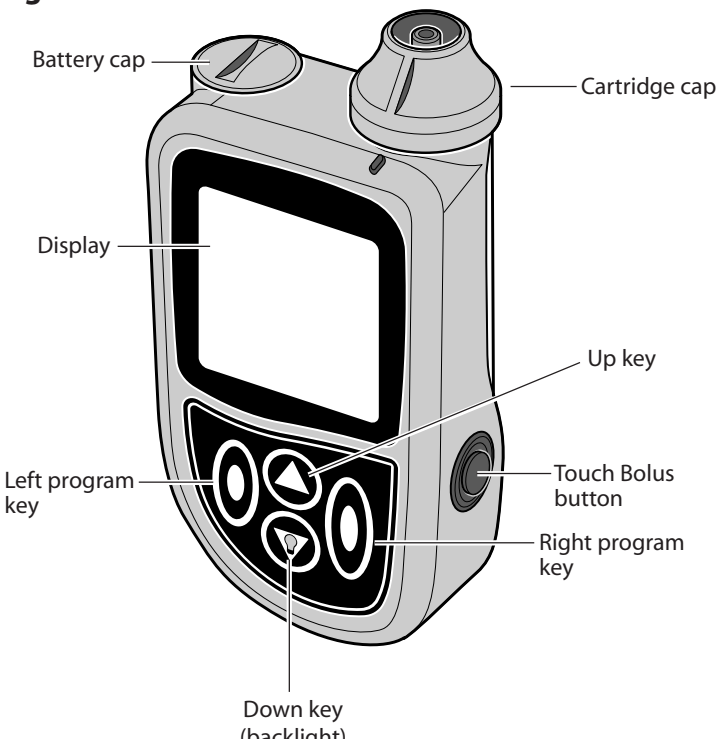
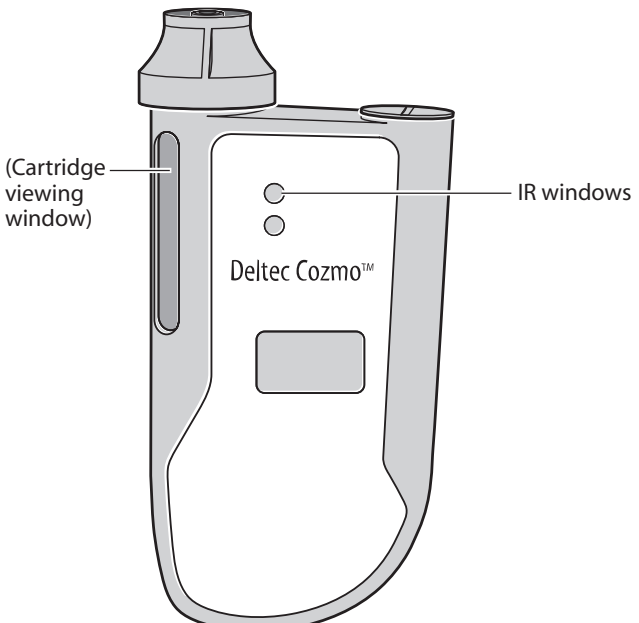


Figure 2



Description of features and buttons

Battery cap (Figure 1)
Holds the battery in place in the battery compartment. The pump uses one "AAA" (IEC LR03) alkaline battery. The approximate amount of battery life is displayed in the home screen, and an alarm is given when battery power is low. Keep extra batteries on hand.

Display (Figure 1)
The display (also referred to as the screen) shows all the programming, operating and alarm/alert information for the pump.

Programming keys (Figure 1)
There are 2 keys on the front of the pump right below the display that do not have any names or symbols on them. These are the programming keys. They have different functions, depending on where you are in a menu. In the display right above each key is a short description of what happens if you press it. Always look to the display above each key to see what the key is used for.

and keys (Figure 1)
The and keys are used to move around in menus, and to program amounts. Whenever you can use the up and down keys, the symbol is shown in the bottom, middle part of the display. When you are at the top or bottom of a menu and only 1 of the keys can be used, and the symbol will change to or , respectively.

Touch bolus button (Figure 1)
If the Touch Bolus feature is turned on, press the Touch Bolus button to program and deliver a bolus.

Cartridge cap (Figure 1)
Once you load a filled cartridge into the compartment, press and turn the cartridge cap over the top of it to hold it firmly in place. You can look at the cartridge viewing window (Figure 2) to make sure the cartridge is properly loaded, and to periodically check the amount of insulin left in the cartridge.

Infrared (IR) windows (Figure 2)
The IR windows allow the pump to communicate with a computer. Your computer must have an IR adapter and My Treatment Assistant™.

Features

Vibration alert

If you don't want the pump to beep during alarms and alerts, you can program it to vibrate instead. This feature can be used in meetings, classrooms, etc. If you choose Vibrate, the "beep" that accompanies each key press is also disabled.

Occlusion (blockage) sensor

The occlusion sensor continuously tests for blockage that prevents insulin from being delivered.

Cartridge sensor

There is a sensor in the cartridge chamber that has 2 functions. It senses when a cartridge is correctly loaded in the chamber. If the cartridge becomes loose or detached during use, the sensor causes an alarm to occur. When you load a new cartridge into the pump, the sensor also measures how much insulin is in the cartridge, and displays this information in the upper left part of the home screen.

Watertight

As long as the pump's labels and outer shell are intact the Deltec Cozmo™ Insulin Pump is watertight, so you do not have to remove the pump when showering or bathing, and allows unlimited swimming activities.

When diving, the pump is watertight to a depth of 8 feet (2.4 meters) for 30 minutes or 12 feet (3.6 meters) for 3 minutes. You will need to discuss the use of a watertight dressing on your access site with your health-care provider.

History

The pump has a History feature that displays a variety of delivery history information. You can decide which reports you want displayed. Information regarding History is included in the History & Communications chapter of this manual.

Description of pump display & menus

All programming, operating and alarm/alert information is shown in the display. Programming of the pump is menu driven, like a cell phone or ATM. Page 1 of the "**home screen**" shows the current basal pattern and rate. Page 2 shows the last bolus information.

Additionally, you can use a computer and My Treatment Assistant™ to customize certain screens and settings on your pump. At the upper left of the home screen, you can input your name or other information in place of the "Cozmo" name. On page 3 of the home screen, you can input important emergency information and phone numbers (or whatever information you want).

A variety of symbols appear on screen. For example, in the main pump menu, each menu item is accompanied by a visual symbol. Also, any time you have to answer a question before proceeding, the question appears on the screen accompanied by [?]. Alarms and alerts are accompanied by [!]. If the pump is performing a task which takes a little time, you will see ⧗.

When you are at the home screen, and no keys or buttons are pressed for 15 seconds, the screensaver display appears (see Figure 3). Press any key on the keypad to deactivate the screensaver and return to the home screen (pressing the ▽ key turns on the screen backlight; the backlight automatically turns off when the screensaver reactivates; when the motor is running, the backlight blinks). The screensaver allows the pump to save on battery power.

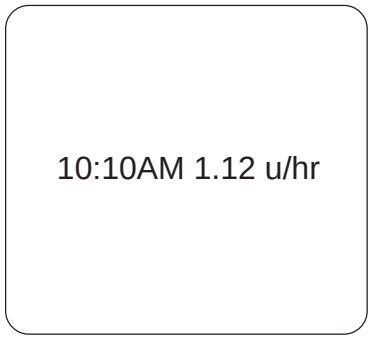
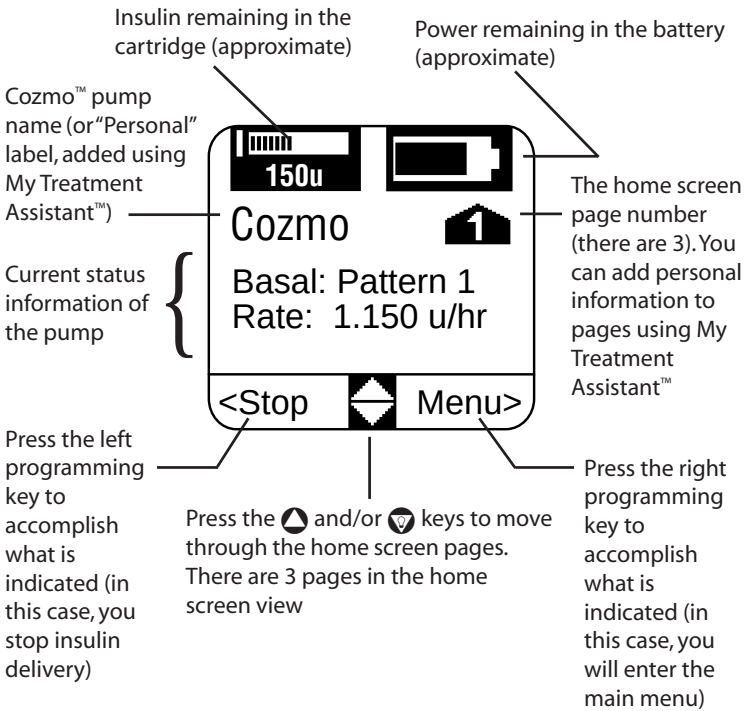


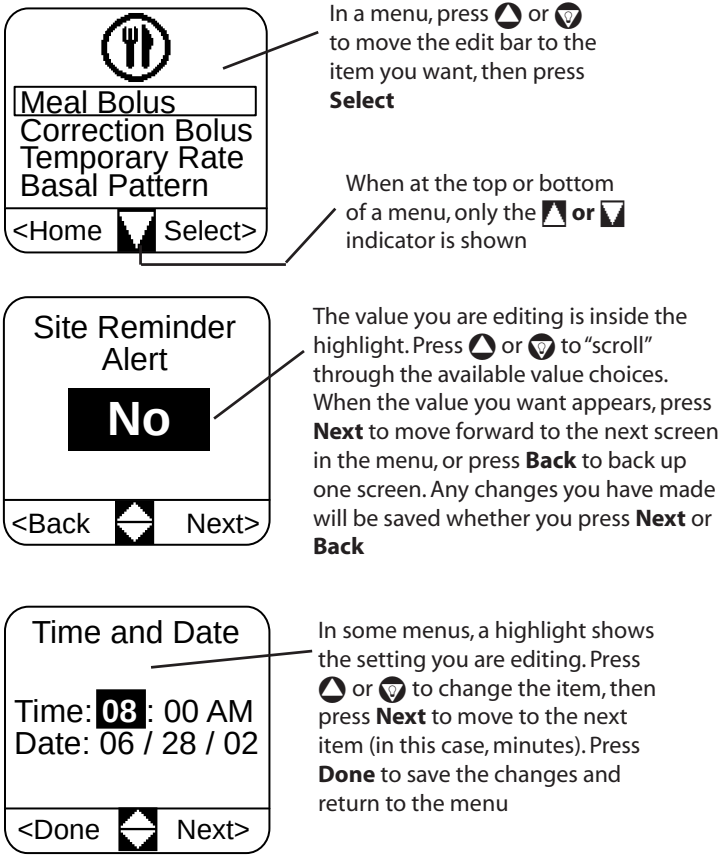
Figure 3

To choose a menu item, press the △ or ▽ key until the edit bar is over the item you want. To program a value (once inside a programming menu), press the △ or ▽ key until the value you want is in the display.

To save a value or setting, press **Next** to move forward to the next screen of the menu, or press **Back** to back out of the menu (for some "sub-menu" items, you need to press **Done**). For this reason, pump programming has a "time-out" feature. If you start to make a change to a value/setting, and then are unsure you want to follow through with the change, wait 45 seconds, and the change is canceled and the original value/setting returns to the screen.


Insulin remaining in the cartridge (approximate)
Power remaining in the battery (approximate)
Cozmo™ pump name (or "Personal" label, added using My Treatment Assistant™)
150u
Cozmo
1
Current status information of the pump
Basal: Pattern 1
Rate: 1.150 u/hr
The home screen page number (there are 3). You can add personal information to pages using My Treatment Assistant™
<Stop
Menu>
Press the left programming key to accomplish what is indicated (in this case, you stop insulin delivery)
Press the ▲ and/or ▼ keys to move through the home screen pages. There are 3 pages in the home screen view
Press the right programming key to accomplish what is indicated (in this case, you will enter the main menu)

Page 1 of the "home screen"


Meal Bolus
Correction Bolus
Temporary Rate
Basal Pattern
<Home
Select>
In a menu, press ▲ or ▼ to move the edit bar to the item you want, then press **Select**
When at the top or bottom of a menu, only the ▲ **or** ▼ indicator is shown
Site Reminder Alert
No
<Back
Next>
The value you are editing is inside the highlight. Press ▲ or ▼ to "scroll" through the available value choices. When the value you want appears, press **Next** to move forward to the next screen in the menu, or press **Back** to back up one screen. Any changes you have made will be saved whether you press **Next** or **Back**
Time and Date
Time: 08 : 00 AM
Date: 06 / 28 / 02
<Done
Next>
In some menus, a highlight shows the setting you are editing. Press ▲ or ▼ to change the item, then press **Next** to move to the next item (in this case, minutes). Press **Done** to save the changes and return to the menu

Sample "menu" screens

Deltec accessories

Deltec offers a variety of products for use with your pump. A complete list of accessories with ordering information is included in the materials supplied with your pump.

Cartridge

You must use the Deltec Cozmo™ 3mL (300 unit) Insulin Cartridge (reorder number 21-1750) with the pump. Deltec cartridges are latex free.

☞ Caution: Use only Deltec Cozmo™ 3mL Insulin Cartridges; other manufacturers' products will not work with the Deltec Cozmo™ pump.

Infusion sets

Deltec offers soft "catheter" infusion sets (the access device you insert into your body is a small cannula, or tube). Catheter sets are inserted with a small needle which is removed after insertion. All Deltec infusion sets are latex free.

☞ Warning: Deltec infusion sets are recommended for use with this pump. Pump operation and accuracy may not be assured if you use other manufacturers' products.

Infrared (IR) adapter

In order to communicate with the pump using My Treatment Assistant™, your computer must have IR capability. You can purchase an IR adapter (reorder number 21-1780) from Deltec. This adapter can be connected via a USB port.

Before using the pump for the first time

Inserting a battery, programming the regional settings (if required), and setting the time and date are the first things you need to do when you get your pump. During typical use, you can expect an alkaline battery to last approximately 1 month (the "**Vibrate**" alert uses up battery power faster).

Insert a battery

1. Put the edge of a coin into the slot on the battery cap and turn it counterclockwise (left) to open it (see Figure 4). Remove the old battery. Discard used batteries according to local laws and requirements.
2. Insert one "AAA" (IEC LR03) alkaline battery into the compartment, making sure the **+** side goes in first (see Figure 5); if you insert the battery wrong, the pump will not start.

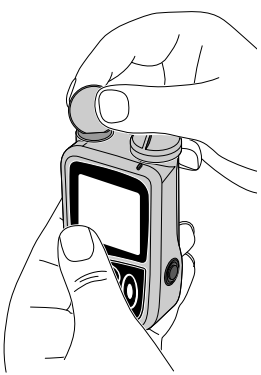


Figure 4

☞ **Caution: Do not use NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries.** They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

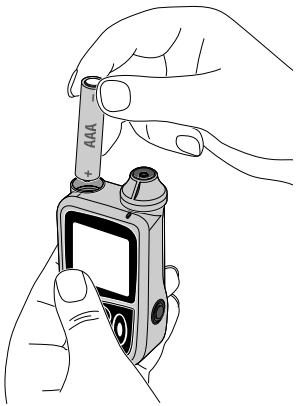


Figure 5

3. Place the battery cap back over the compartment. Push down and turn the cap clockwise (right). Again use a coin to tighten the cap. Make sure the cap is on tight.

If you insert a new battery and the pump doesn't turn on, check to make sure that the battery is in the correct orientation (the **+** side goes in first). If it still doesn't turn on, try a new battery.

Once the battery is correctly inserted, the pump turns on automatically and performs "self tests" to make sure all the systems are working properly, and then stops at the "home screen."

Self Tests

During the self tests, the pump's internal computer performs tests on all the major hardware, computer, and electronic systems.

☞ **Warning: If there are any system problems, the pump will stop the tests and display an alarm screen letting you know there is a problem. If this happens, do not use the pump.**

After installing a new battery, watch the pump's display and verify the following:

- The internal computer's software version appears, as well as the pump serial number (SN) and last error code (if any).
- The entire display becomes a darker gray. Look for any blank or incomplete areas, which indicates a broken display. The display then briefly turns off.
- The pump's internal computer tests the major hardware, computer and electronic systems. If there is a problem with any system, an alarm occurs and you will not be able to start insulin delivery.

When the self tests are complete, power up ends and the pump beeps 6 times and stops at the home screen.

The first time you insert a battery and your new pump performs the self tests, you will see the following alert screens:

• a screen will appear that reads "**Program Defaulted** Set time and date". Program the current time and date by pressing ▲ and ▼ to set the highlighted value, then pressing **Next** to move through the sequence. When the time and date are correct, press **Done**.

• Next you will see a screen that reads "**Program Defaulted** You must program the pump". Press **OK**.

• After the pump beeps 6 times, a screen that reads "**Cartridge removed** Insert filled cartridge to continue delivery" is displayed. Press **OK**; the pump goes to the **Load** menu. If you are ready to load a cartridge, follow the steps indicated starting on page 35. If you aren't ready to load a cartridge yet, press **Done**.

NOTE: The pump has a built-in internal battery that powers the clock and allows the pump to store the programs and history (see page 107) which is charged by the AAA alkaline battery. If your pump has not been charged for awhile, you may see a screen that reads "**Program Defaulted** Setup of cartridge volume required, with no cartridge present, press Next". Make sure no cartridge is loaded into the pump and press **Next**.

Attach the belt clip (Optional)

Slide the pump into the belt clip with the keypad facing out (see Figure 6).

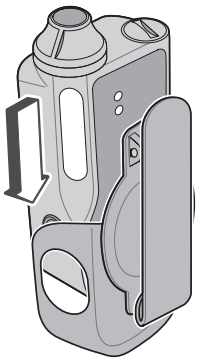


Figure 6

You can rotate the clip to whatever position is most comfortable for you (see Figure 7).

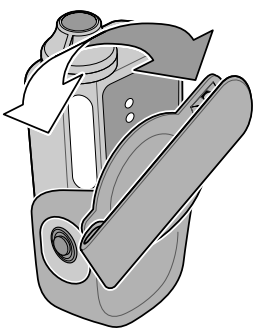


Figure 7

Pinch the clip open and attach it to your clothing waist band or belt (see Figure 8).

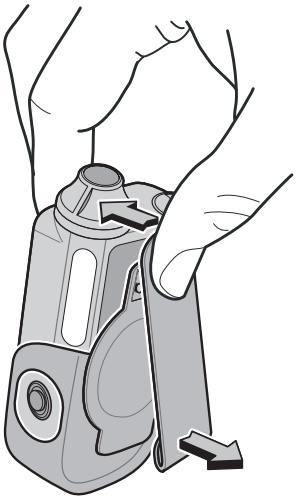


Figure 8

Pump settings

The **Pump Settings** menu allows you to perform certain setup functions, such as setting the time and date, setting up how the pump alarms, and personalizing certain features. (Program Lock is also included in the **Pump Settings** menu, but is discussed later in this chapter on page 32.)

☞ **Warning: The time and date must be set correctly, since basal patterns are time-based, and all of the history is stored based on time and date.** Occasionally you will need to reset the time, for example, during daylight savings time or to adjust for a different time zone.

At the home screen, press **Menu**. Then, press ▼ to choose **Pump Settings**, then press **Select**.

Once inside the menu, you can choose between the various items. Once you have entered a menu item, you can either make a change to an item (use the ▲ and ▼ keys until the setting you want is displayed, then press **Next**), or press **Next** to accept the displayed value. **Personalize** is a sub-menu, and includes deciding how, if or when certain pump alerts occur, which history reports are displayed in the history menu (this is discussed in chapter 6, page 99), programming the regional setting, and setting up Delivery (Delivery settings are discussed in later chapters).

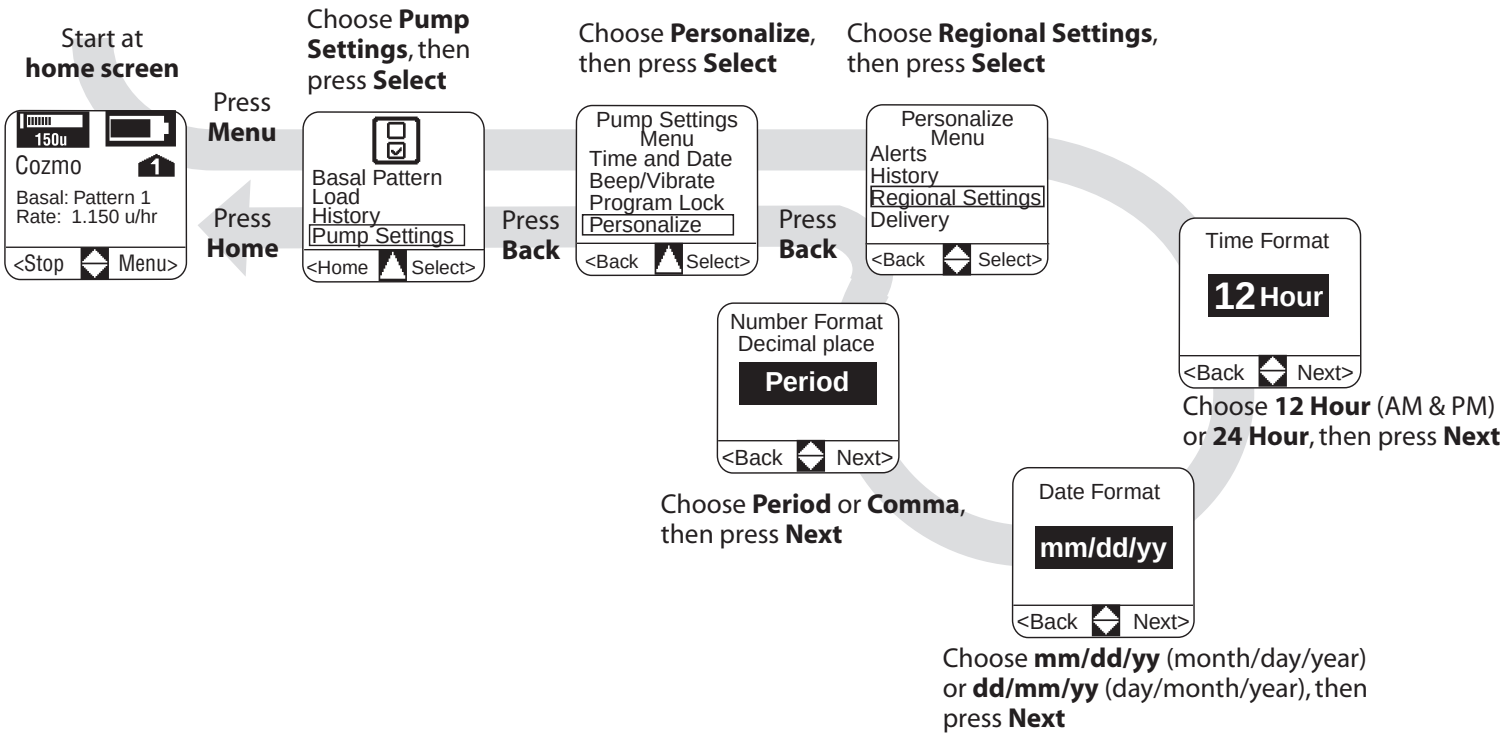
Regional settings

The regional settings determine how certain things are displayed on the pump.

- Time can be displayed as 12 hour (AM and PM) or 24 hour.
- The date can be displayed as month/day/year (mm/dd/yy) or day/month/year (dd/mm/yy).
- The decimal point can be displayed as either a Period (xx.xx) or as a Comma (xx,xx).

When the pump is built, the default settings are: Time format: 12 Hour; Date format: mm/dd/yy; and Number format: Period. If these are correct for your region, you can skip this section. If you use different settings, follow the instructions on the next page.

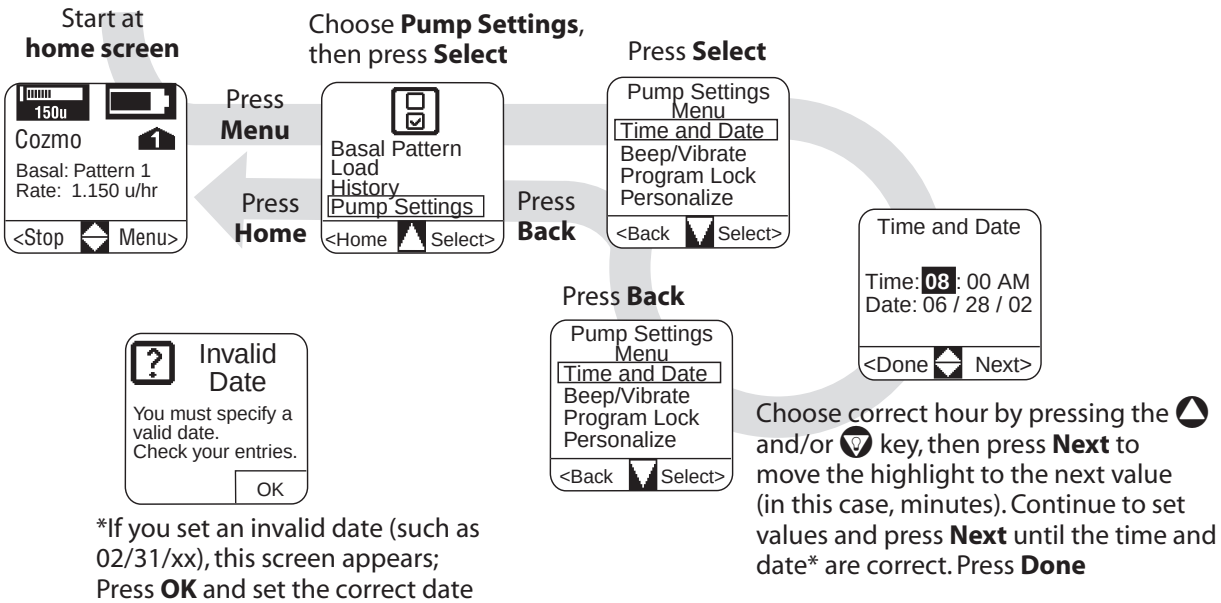
Regional Setting



Time and date

☞ Warning: The time and date must be set correctly, since basal patterns are time-based, and all of the history is stored based on time and date. Occasionally you will need to reset the time, for example, during daylight savings time or to adjust for a different time zone.

NOTE: If your pump is programmed to display a site reminder alert (see page 28), resetting the time may cause that alert to occur sooner or later than anticipated (up to 24 hours), depending on how far forward or back you set the time.

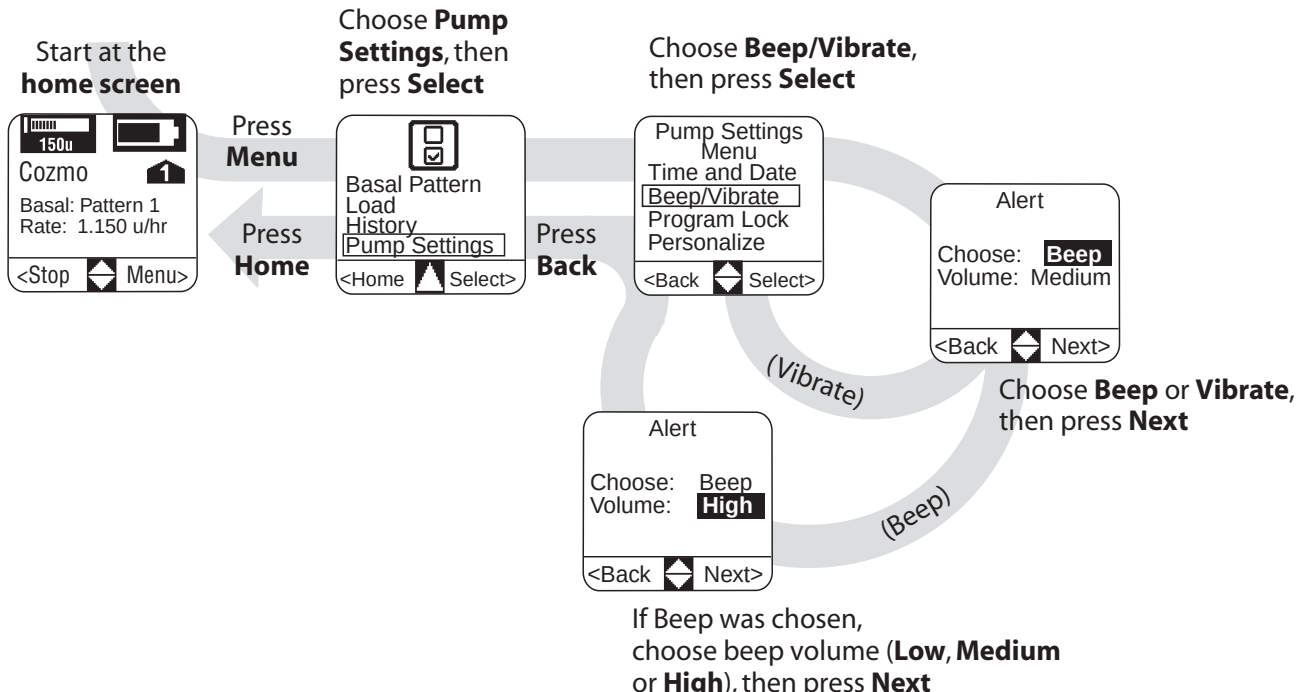


*If you set an invalid date (such as 02/31/xx), this screen appears; Press **OK** and set the correct date

Choose correct hour by pressing the ▲ and/or ▼ key, then press **Next** to move the highlight to the next value (in this case, minutes). Continue to set values and press **Next** until the time and date* are correct. Press **Done**

Beep or Vibrate

Choose **Beep** or **Vibrate*** to signal alarms and alerts. Then, if using **Beep**, decide how loud the beep is. **Low** is quietest and **High** is loudest. It is factory preset to **High**.



*Note that **Vibrate** uses up batteries much faster.

Personalizing alerts

The pump allows you to set up certain alarms and alerts the way you prefer. These alerts/alarms are associated with treatment considerations, personal preference and safety, and can be personalized uniquely for each user. Discuss with your healthcare provider what uses and settings are appropriate for you. All of the settings are factory preset, so you are not *required* to change any of them.

Alert for low cartridge: determines when the pump alerts you to an almost empty cartridge. Decide how much insulin should be left when the alert occurs (5 to 50 units). It is factory preset to **20u**. (Choosing a higher number of units will give you more time between the low cartridge alarm and the empty cartridge alarm.)

Delivery limit alarm: the pump monitors how much insulin is delivered over an hour, and if you try to exceed the maximum amount programmed here, it gives an alarm. Decide, with help from your healthcare provider, the maximum units that can be delivered over an hour (1 to 100 units). It is factory preset to **40u**.

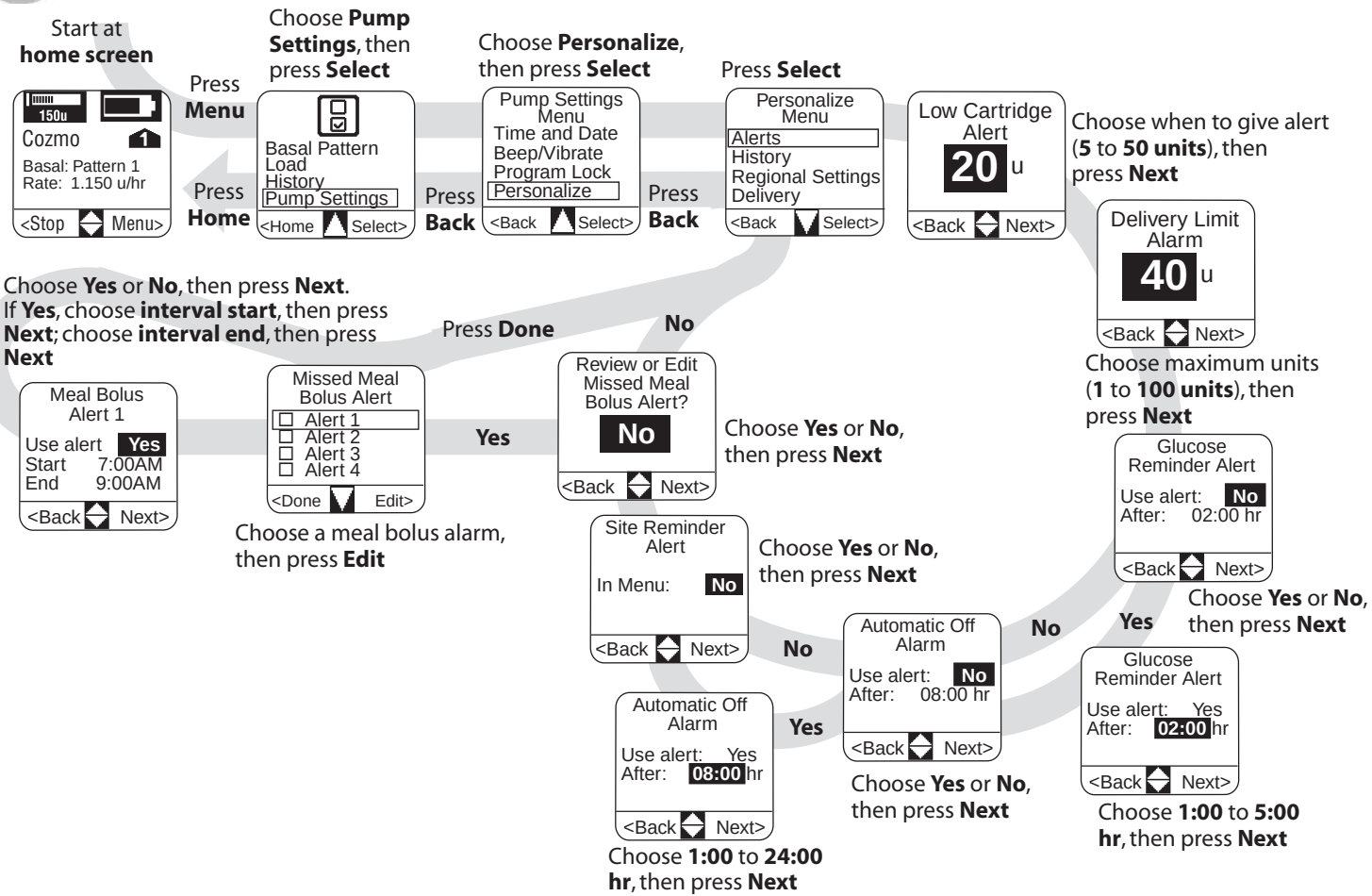
Glucose reminder: optional alert reminds you to check your BG level (based on when you last loaded a cartridge or delivered a bolus). First, decide if you want a reminder; then, if **Yes**, decide when to give it (1 to 5 hours after loading a cartridge or delivering a bolus). It is factory preset to **No** (reminder not in use).

Automatic off: this is a feature that causes the pump to alarm, display a message, and stop insulin delivery if no keys or buttons are pressed for a specified period of time. (Using My Treatment Assistant™, you can create a personalized alarm message which appears should this alarm occur.) First decide if you want to use the alarm; then, if **Yes**, determine a time frame for the alarm to occur at (1:00 to 24:00 hours). It is factory preset to **Off** (alarm not in use).

Display site reminder in menu: optional alert determines whether a screen is added to the **Load** menu allowing you to set a reminder for when it is time to change your infusion set and access site. It is factory preset to **No** (reminder not in use).

Missed meal bolus alerts: missed meal bolus alerts can be used to remind you about possible missed meal boluses. You can review or edit missed meal bolus alerts. On the review screen, a check box (☑) appears next to missed meal bolus alerts that are active. To edit a missed meal bolus alert, press **Edit**. Then, decide whether you want the alert and, if you do, when it

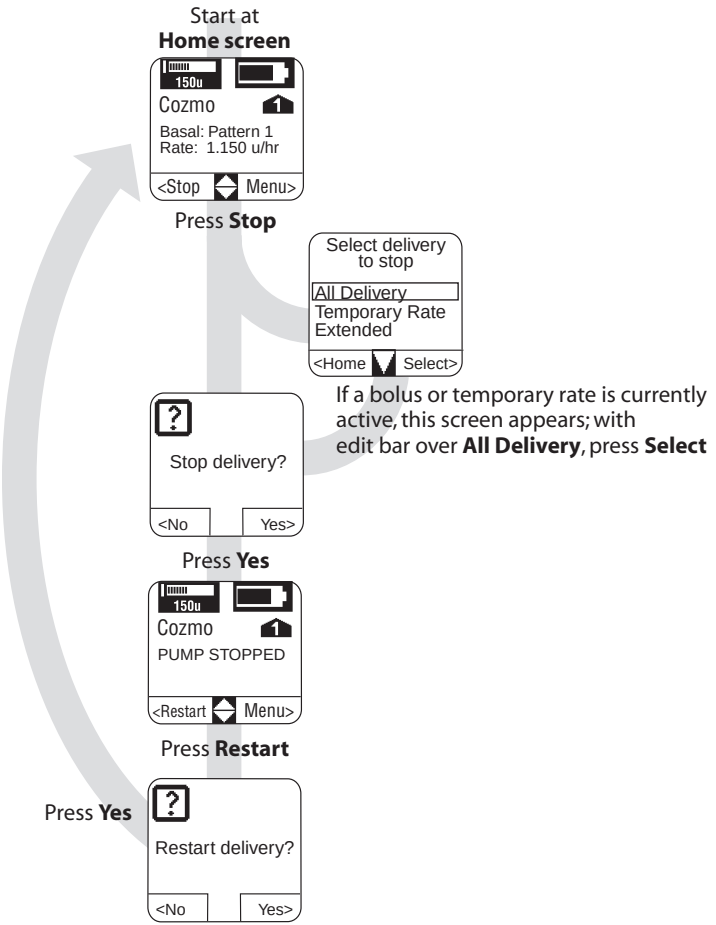
should occur. For example, if you eat breakfast every day between 7:00AM and 9:00AM, you could select 6:45AM for the “Start” time, and 9:15AM for the “End” time. Then if the pump detects that no bolus was delivered during that period, the pump will give an alert.


Start at **home screen**
150u
Cozmo
1
Basal: Pattern 1
Rate: 1.150 u/hr
<Stop Menu>
Press **Menu**
Press **Home**
Choose **Pump Settings**, then press **Select**
Basal Pattern
Load
History
Pump Settings
<Home Select>
Press **Back**
Choose **Personalize**, then press **Select**
Pump Settings Menu
Time and Date
Beep/Vibrate
Program Lock
Personalize
<Back Select>
Press **Back**
Press **Select**
Personalize Menu
Alerts
History
Regional Settings
Delivery
<Back Select>
Low Cartridge Alert
20 u
<Back Next>
Choose when to give alert (**5** to **50 units**), then press **Next**
Delivery Limit Alarm
40 u
<Back Next>
Choose maximum units (**1** to **100 units**), then press **Next**
Glucose Reminder Alert
Use alert: No
After: 02:00 hr
<Back Next>
Choose **Yes** or **No**, then press **Next**
Yes
No
Glucose Reminder Alert
Use alert: Yes
After: 02:00 hr
<Back Next>
Choose **1:00** to **5:00 hr**, then press **Next**
Automatic Off Alarm
Use alert: No
After: 08:00 hr
<Back Next>
Choose **Yes** or **No**, then press **Next**
Yes
No
Automatic Off Alarm
Use alert: Yes
After: 08:00 hr
<Back Next>
Choose **1:00** to **24:00 hr**, then press **Next**
Site Reminder Alert
In Menu: No
<Back Next>
Choose **Yes** or **No**, then press **Next**
Yes
No
Review or Edit Missed Meal Bolus Alert?
No
<Back Next>
Choose **Yes** or **No**, then press **Next**
Yes
No
Missed Meal Bolus Alert
Alert 1
Alert 2
Alert 3
Alert 4
<Done Edit>
Choose a meal bolus alarm, then press **Edit**
Meal Bolus Alert 1
Use alert Yes
Start 7:00AM
End 9:00AM
<Back Next>
Choose **Yes** or **No**. If **Yes**, choose **interval start**, then press **Next**; choose **interval end**, then press **Next**
Press **Done**

Stopping and restarting insulin delivery

You can stop and restart insulin delivery from the home screen.

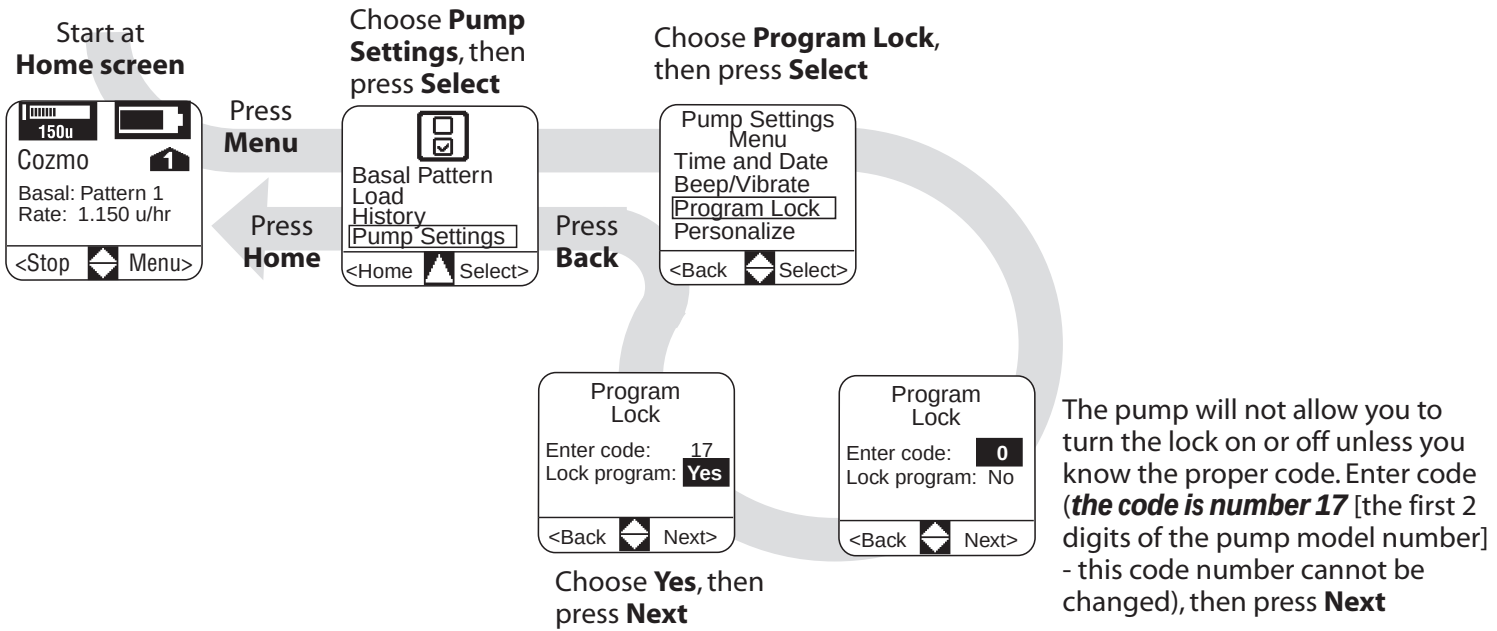
☞ **Warning:** When stopping delivery, remember that since the pump uses only short-acting insulin, your insulin level will start to fall and blood glucose level to rise very quickly (in as little as 90 minutes). **You must test your blood glucose when stopping delivery for any length of time.**



Program Lock

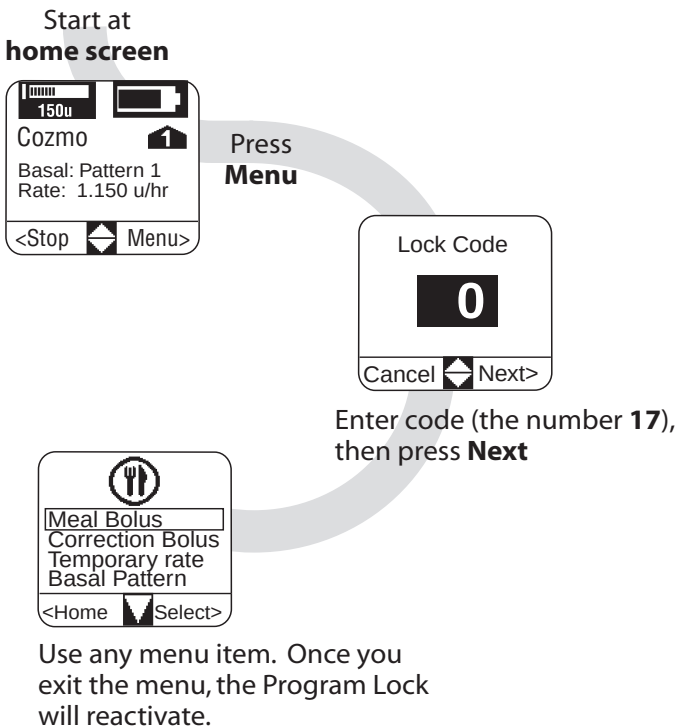
Program Lock allows you to prevent anyone from entering the menu without the proper code. You can still troubleshoot most alarms.

☞ **Warning: Once the pump is locked, you will not be able to enter the menu without the proper code.** Touch Bolus is also not allowed when the pump is locked. Make sure there is someone around who knows the proper code.


Start at **Home screen**
150u
Cozmo
1
Basal: Pattern 1
Rate: 1.150 u/hr
<Stop
Menu>
Press **Menu**
Choose **Pump Settings**, then press **Select**
Basal Pattern
Load
History
Pump Settings
<Home
Select>
Press **Home**
Press **Back**
Choose **Program Lock**, then press **Select**
Pump Settings Menu
Time and Date
Beep/Vibrate
Program Lock
Personalize
<Back
Select>
Program Lock
Enter code: 17
Lock program: Yes
<Back
Next>
Choose **Yes**, then press **Next**
Program Lock
Enter code: 0
Lock program: No
<Back
Next>
The pump will not allow you to turn the lock on or off unless you know the proper code. Enter code (***the code is number 17*** [the first 2 digits of the pump model number] - this code number cannot be changed), then press **Next**

Unlocking the menu

You can use an item in the menu without turning off the Program Lock by following the procedure below. To turn the Program Lock off, you need to follow the procedure on page 32, but at the "Program Lock / Lock program" screen, choose **No**.



Notes:

What's In This Section?

Deltec CoZmo™

The Freedom to Be You.™

- Loading a cartridge
- Meal bolus
  - Standard bolus (units of insulin): setup
  - Standard bolus: delivery
  - Carbohydrate bolus: setup
  - Carbohydrate bolus: delivery
- Basal patterns
  - Personalizing basal patterns
  - Editing basal patterns
  - Using basal patterns

Loading a cartridge

The Load feature in the pump menu takes you through each step needed to load a filled cartridge in the pump and start delivering insulin.

☞ Warning: Always use the pump's Load feature when starting a new cartridge. This will assure that the cartridge is properly loaded and the tubing and access device are filled with insulin.

☞ Warning: Whenever you load a new cartridge and attach an infusion set, you must test your BG level within 1 to 2 hours to make sure that insulin is being properly delivered. If you do not test within this time-frame, and insulin delivery is delayed or blocked, you may develop hyperglycemia. If desired, you can use the Glucose Reminder alert to remind you to test your BG level (see Personalizing Alerts, page 28).

☞ Warning: Always use "aseptic" technique, particularly when working with the cartridge, infusion set, catheter and access site. An increased risk of skin infection is associated with pump use, as the access device remains in place for 2 or more days (see "Aseptic Technique," page 9).

Supplies required

In addition to the pump, you will need:

- 1 vial short-acting, U100 insulin that is room temperature (if the insulin is too cold, it may form bubbles in the cartridge and the tubing)
- 1 Deltec Cozmo™ 3mL Insulin Cartridge
- 1 Deltec insulin infusion set
- Antiseptic solution for preparing access site (I.V. Prep®, isopropyl alcohol, Betadine®, Hibiclens®, etc.)
- Medical tape and/or sterile dressing for securing access device to your body

☞ Warning: Always read the instructions for use provided with the insulin, catheter, infusion set, and any other accessory used with the Deltec Cozmo™ Insulin Pump.

1. Filling the cartridge

Use aseptic technique (see page 9).

Fill the cartridge according to the *Instructions for Use* supplied with the cartridge.

2. Attaching an infusion set and loading a filled cartridge into the pump

☞ Warning: To avoid accidentally infusing insulin, disconnect the infusion set tubing from the access device (or site) before removing a used cartridge or replacing an infusion set. Never use the pump's "load cartridge" or "fill tubing" features while an infusion set is connected to your body. You could deliver an unintended dose of insulin, resulting in low blood glucose (hypoglycemia).

1. Turn the cartridge cap counter-clockwise (left) approximately 1/4 turn and remove it from the pump (see Figure 9). If required, remove the used cartridge (you may get the "Cartridge Removed" alert; press OK). NOTE: turning the cartridge cap may also turn the cartridge, so it may already be disconnected from the pushrod when the cap is removed. If not, turn the cartridge 1/4 turn to the left to disconnect it from the pushrod.

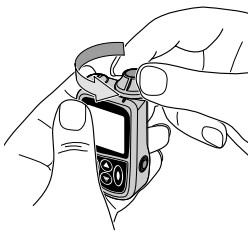


Figure 9

2. Place the cartridge cap over the tip of the new cartridge; remove the protective cap from the luer end of the infusion set and insert the luer through the hole in the cap and firmly tighten it onto the tip of the cartridge (see Figure 10).

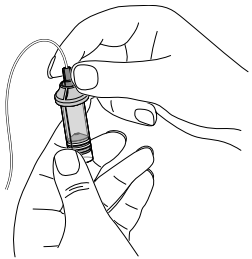


Figure 10

☞ Warning: If not properly tightened, insulin could leak from this connection and disrupt delivery (the insulin that leaks out is not being delivered into your body like it should be and, depending on how much insulin is leaking, could cause your BG level to rise). Signs of leakage can also mean opportunity for contamination leading to infection.

3. Insert the new cartridge into the cartridge chamber (see Figure 11). Gently turn the cartridge clockwise (right) about 1/4 turn to fasten it onto the pushrod (you may need to first turn the cartridge until it drops onto the pushrod).

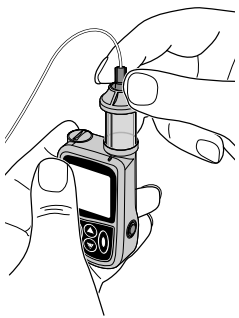
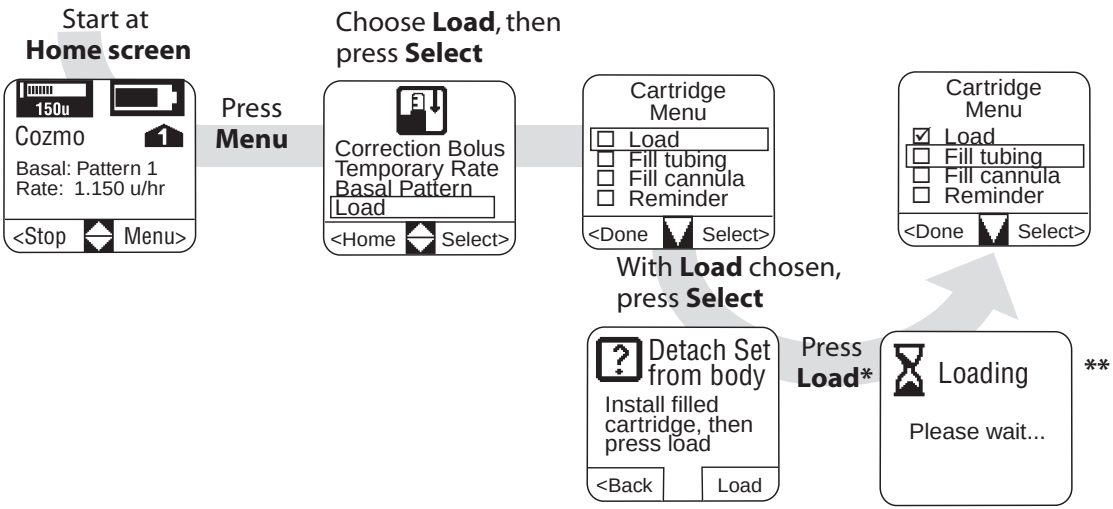


Figure 11

4. Open the pump's Load menu and load cartridge.

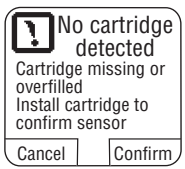
NOTE: You will not be able to load a cartridge that contains less than 20 units (the sensor may have trouble sensing the cartridge amount).

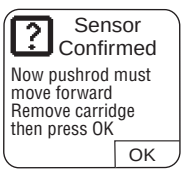


* See the next page for additional screens which may appear when your press Load.

** See the next page for additional screens which may appear after the "Loading" screen.

*In order for the pump to assure that the cartridge is correctly connected to the pushrod, the pushrod must start in a forward position. If it is not far enough forward when you press **Load, or if you attempt to load a cartridge that contains less than 20 units of insulin**, the screens shown at left will appear. Remove the cartridge, then press **OK**. The pushrod moves forward, then you return to the cartridge menu. If your cartridge contains less than 20 units of insulin, you will need to start with a new filled cartridge. With **Load** still chosen, press **Select**.





**If, during the loading process, you intentionally or accidentally remove the cartridge, or if the cartridge is too full (more than 300 units), the screens shown at left will appear. The pump needs to check to make sure that the cartridge sensor is working properly.

- If the cartridge is not installed, install it;
- if a cartridge is installed make sure it is not too full (fill with no more than 300 units). Press down gently on the cartridge (this will push excess insulin into the infusion set tubing). Press **Confirm**. The pump will confirm that the sensor is working properly. (If the sensor is not working, you will get this message repeatedly and your pump will need to be serviced). If the sensor is confirmed, you must remove the cartridge and press **OK**. The pushrod moves forward, then you return to the cartridge menu. With **Load** still chosen, press **Select**.

5. Verify, by looking through the cartridge viewing window, that the cartridge is properly attached to the pushrod. Fasten the cartridge cap back onto the pump. Make sure the rib on the cap lines up with the rib on the pump, indicating the cap is secured (see Figure 12).

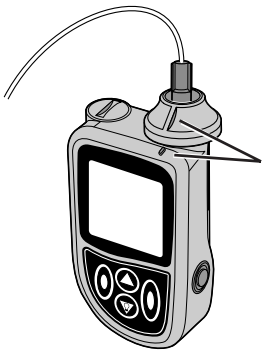
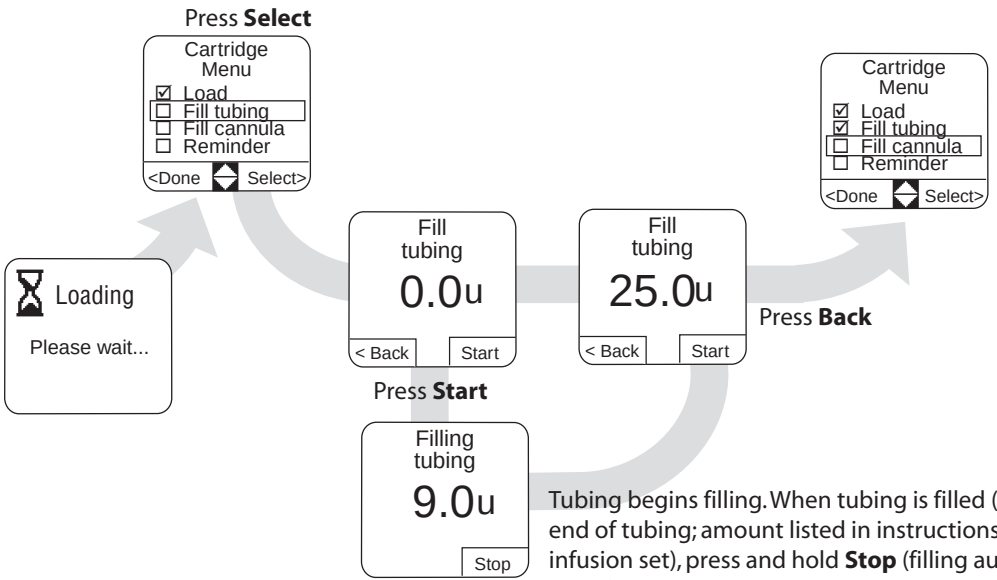


Figure 12

3. Fill the tubing

Filling forces insulin from the cartridge into the infusion set tubing and pushes air out of the tubing. Filling is complete when you see insulin come out of the end of the tubing and all air is removed. The amount of insulin used to fill the tubing is not counted as part of your daily totals.

☞ Warning: Never use Fill tubing when the infusion set is connected to your body, or you could deliver an unintended bolus.



Tubing begins filling. When tubing is filled (insulin drips from end of tubing; amount listed in instructions supplied with infusion set), press and hold **Stop** (filling automatically stops at 30u; if you need more than 30u, press **Start** again).

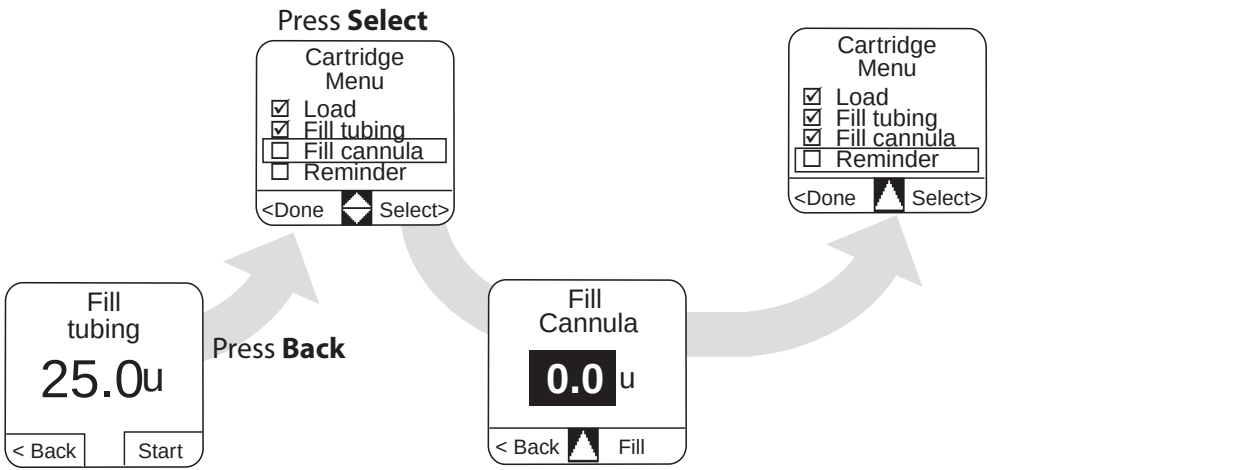
4. Choosing an access site and inserting the access device

- Choose an access site. Anywhere you would normally inject insulin can be used as an access site, including your abdomen, hips, buttocks, upper thighs, etc. Choose an area where you have a sufficient layer of subcutaneous fat. Avoid areas that may be rubbed by clothing (waistband, etc.), and stay at least 2 inches (5cm) away from your belly button. Your healthcare provider can help you with site selection and give you information about properly caring for your site.
- Swab the selected access site with an antiseptic solution. Allow it to dry. Insert the infusion set cannula or needle according to the *Instructions for Use* supplied with the infusion set. Once it is properly inserted, apply a dressing and tape it securely into place.

☞ Warning: Always remove all air from the cartridge and infusion set before starting insulin delivery. Air bubbles in the system can slow or stop insulin delivery. Check all connections carefully for leaks (wrapping a tissue around connections to check for moisture is a good technique), as leakage can slow or stop insulin delivery to the body, and allow an opening for contamination leading to infection. If insulin delivery is slowed or stopped, high blood glucose (hyperglycemia) will result.

5. Fill cannula

Filling the cannula is an important step if you are using an infusion set that has a separate access device (needle or cannula). It delivers a small amount of insulin that fills the access device. If you do not fill the cannula, there is a delay in insulin delivery once the pump is started as the access device fills.

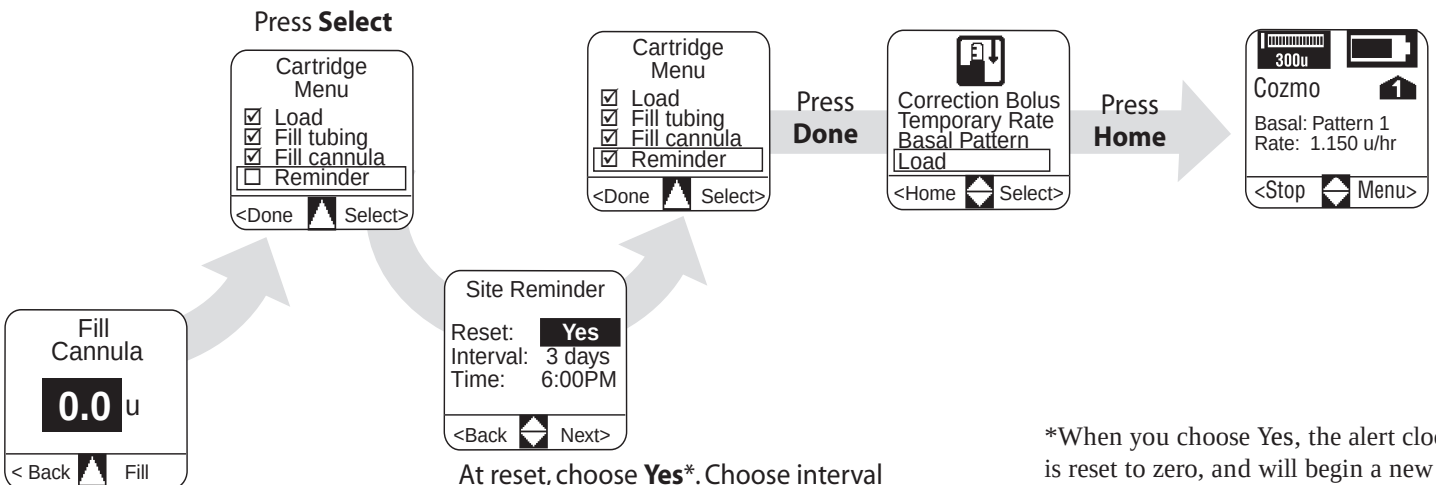


Choose amount needed to fill cannula (listed in instructions supplied with infusion set), then press **Fill** (once you enter an amount here, that amount becomes the "default," and will always be shown in this screen)

6. Set site change reminder and restart delivery

The Site Change reminder screens appear here if turned on in Pump Settings / Personalize / Alert (see page 28). Setting the site change reminder will cause the pump to beep (or vibrate) to remind you that it is time to change your infusion set and access site.

☞ Warning: You should not change your access site right before bed, as you would be unaware of any problems with the site. You must test your BG level 1 to 2 hours after starting a new cartridge to make sure insulin is being properly delivered.



At reset, choose **Yes***. Choose interval between alerts, then press **Next**; choose time, then press **Next**

*When you choose Yes, the alert clock is reset to zero, and will begin a new countdown (in this example, in 3 days at 6:00 PM your pump will give the alert). Choosing No allows the alert clock to continue the countdown from the last time it was reset.

Meal Bolus

☞ Warning: You should receive specific training on programming and delivering a meal bolus. Please carefully read all instructions and talk to your healthcare provider.

There are two different ways to program and deliver a meal bolus, depending on what works best for you. They are:

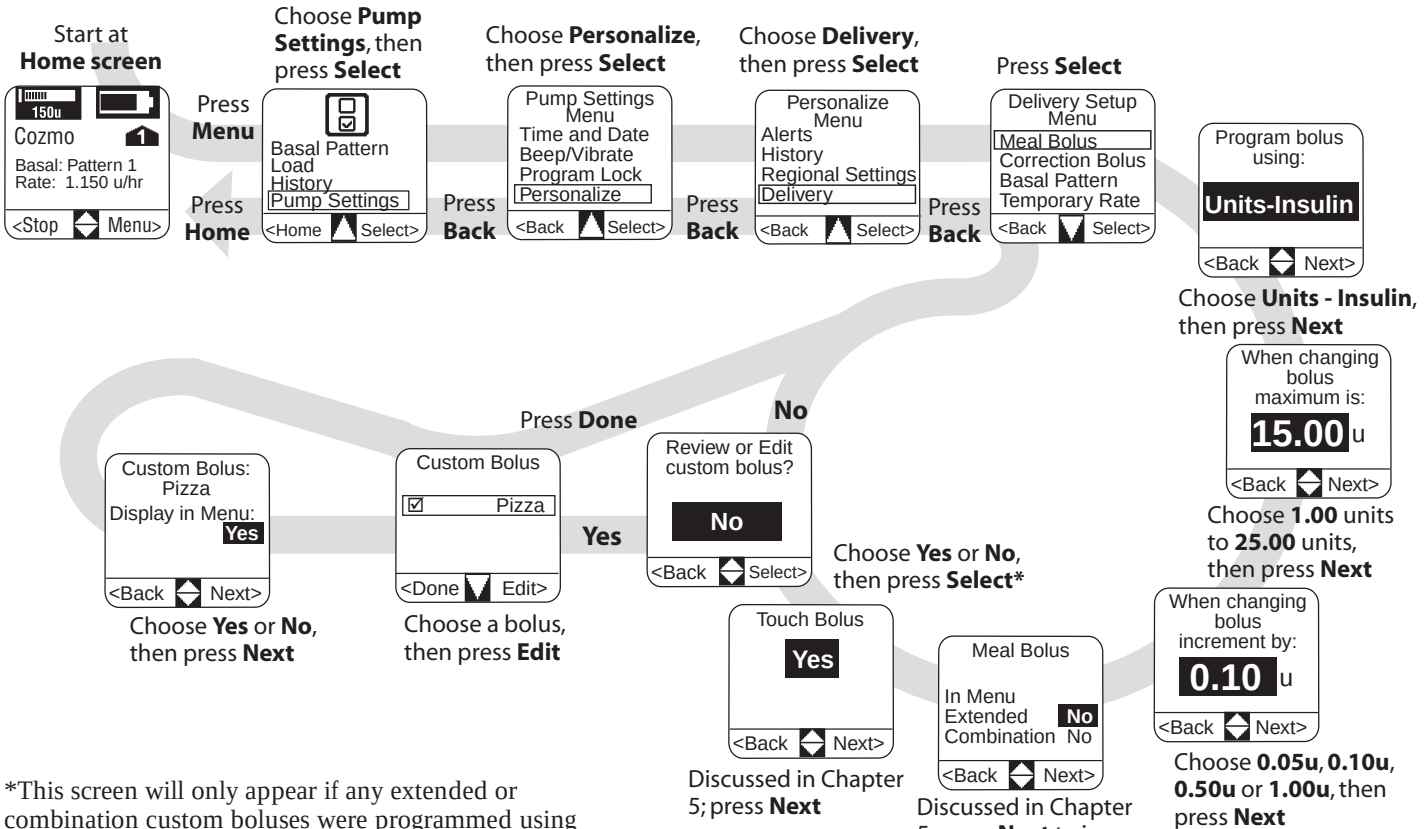
Standard bolus: programmed in units of insulin. You must also decide how you want the pump to "increment," or count when you are programming a bolus.

Carbohydrate bolus: you enter the amount of carbohydrate in your meal or snack, and the pump calculates and recommends how much insulin you need for that meal/snack. You must also decide how you want the pump to "increment," or count carbohydrates when you are programming a bolus.

Many of the screens in the Meal Bolus menu can be personalized using My Treatment Assistant™. If your screens have been personalized, the titles may be different on your pump than those shown here; talk to your healthcare provider about any personalization that was done to your pump.

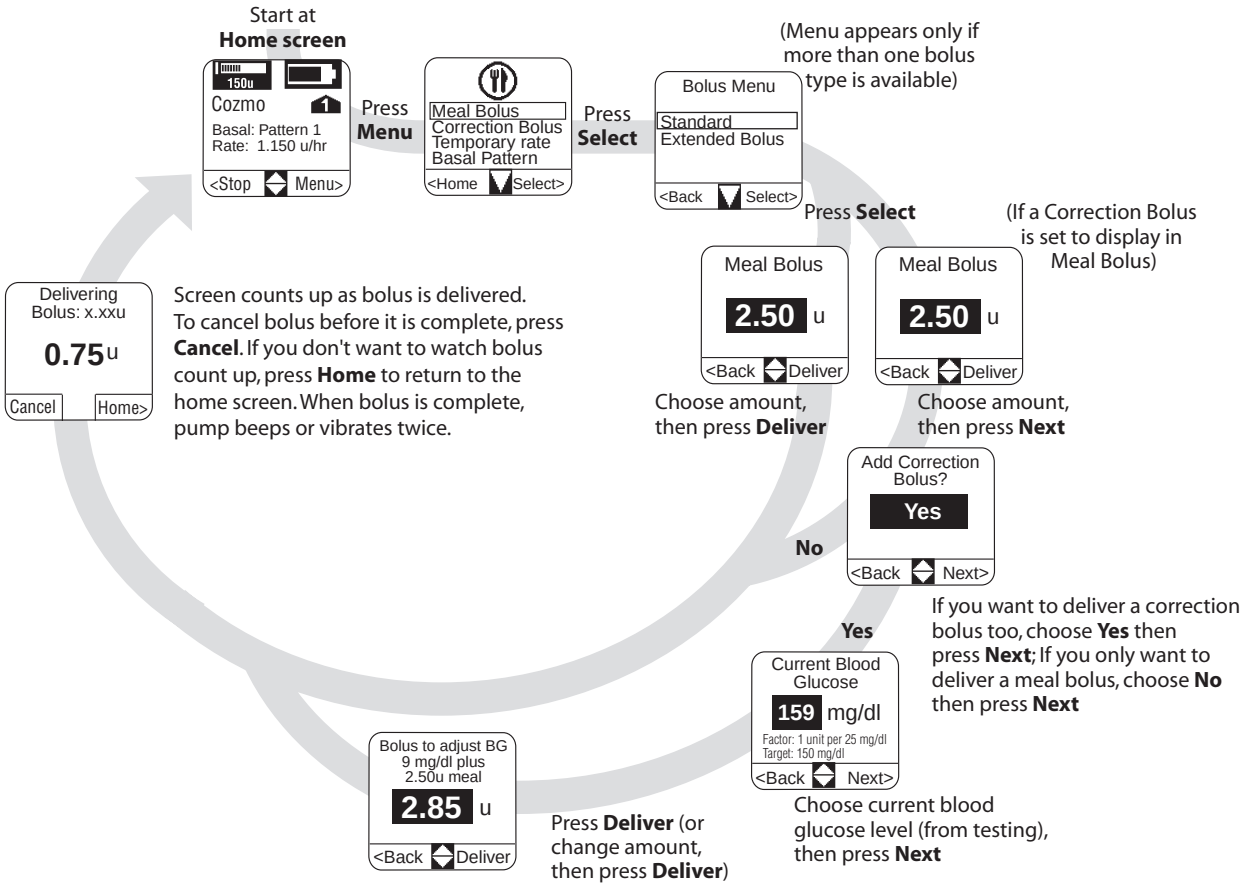
NOTE: Many of the settings you program here will be used by all of the meal bolus types available on the pump (Touch Bolus, Extended Bolus, Combination Bolus and any custom meal boluses). All of the boluses will use the type of bolus selected (Units - Insulin or Grams - Carbs), will have the maximum bolus as programmed here, and will increment using the amount programmed here. The Touch Bolus, Extended Bolus and Combination Bolus are discussed in the Using the Pump - More Features chapter of this manual starting on page 81.

Standard bolus (units of insulin): setup

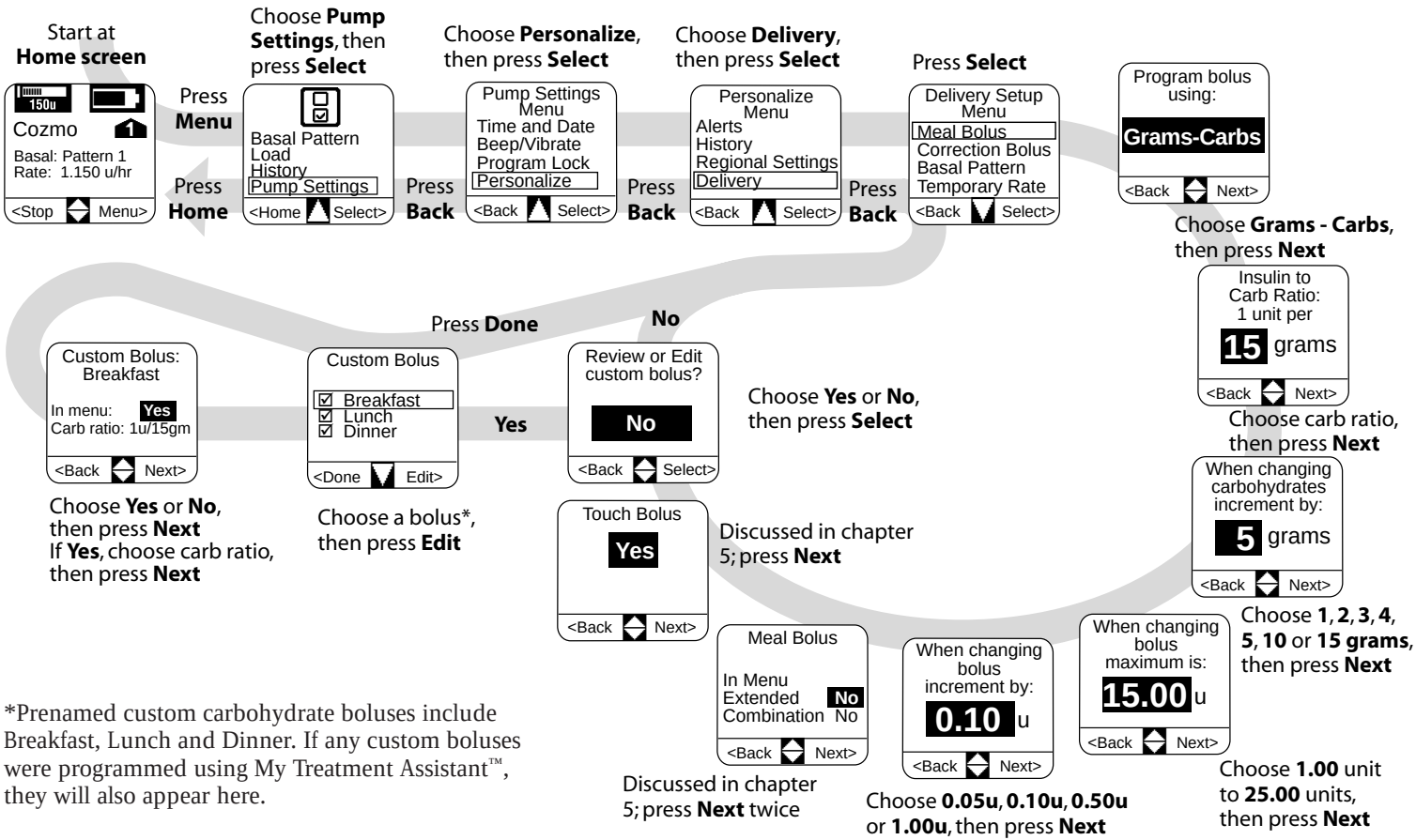


*This screen will only appear if any extended or combination custom boluses were programmed using My Treatment Assistant™.

Standard bolus: delivery

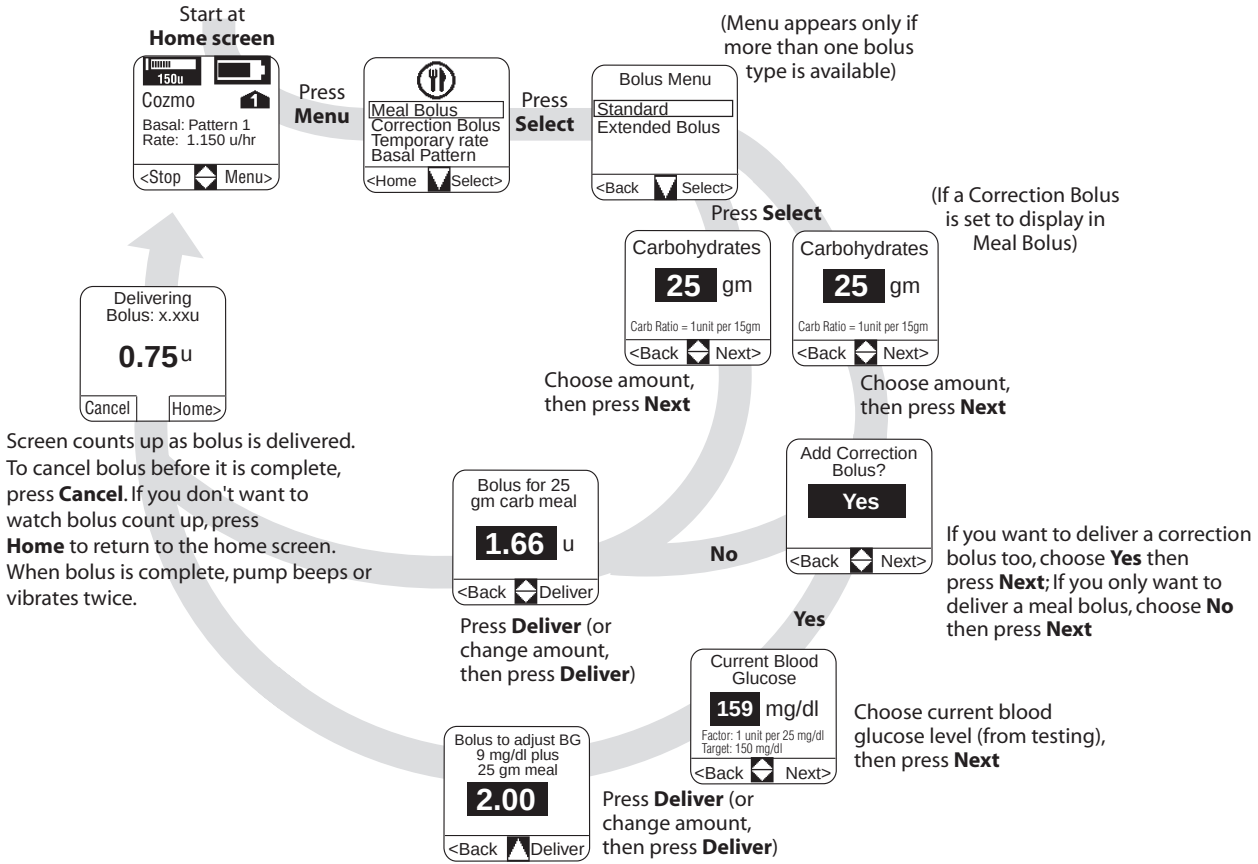


Carbohydrate bolus: setup



*Prenamed custom carbohydrate boluses include Breakfast, Lunch and Dinner. If any custom boluses were programmed using My Treatment Assistant™, they will also appear here.

Carbohydrate bolus: delivery


Start at
Home screen
150u
Cozmo
1
Basal: Pattern 1
Rate: 1.150 u/hr
<Stop Menu>
Press
Menu
Meal Bolus
Correction Bolus
Temporary rate
Basal Pattern
<Home Select>
Press
Select
(Menu appears only if more than one bolus type is available)
Bolus Menu
Standard
Extended Bolus
<Back Select>
Press Select
(If a Correction Bolus is set to display in Meal Bolus)
Carbohydrates
25 gm
Carb Ratio = 1unit per 15gm
<Back Next>
Carbohydrates
25 gm
Carb Ratio = 1unit per 15gm
<Back Next>
Choose amount, then press Next
Choose amount, then press Next
Delivering Bolus: x.xxu
0.75u
Cancel
Home>
Screen counts up as bolus is delivered. To cancel bolus before it is complete, press Cancel. If you don't want to watch bolus count up, press Home to return to the home screen. When bolus is complete, pump beeps or vibrates twice.
Bolus for 25 gm carb meal
1.66 u
<Back Deliver
Press Deliver (or change amount, then press Deliver)
No
Add Correction Bolus?
Yes
<Back Next>
If you want to deliver a correction bolus too, choose Yes then press Next; If you only want to deliver a meal bolus, choose No then press Next
Yes
Current Blood Glucose
159 mg/dl
Factor: 1 unit per 25 mg/dl
Target: 150 mg/dl
<Back Next>
Choose current blood glucose level (from testing), then press Next
Bolus to adjust BG 9 mg/dl plus 25 gm meal
2.00
<Back Deliver
Press Deliver (or change amount, then press Deliver)

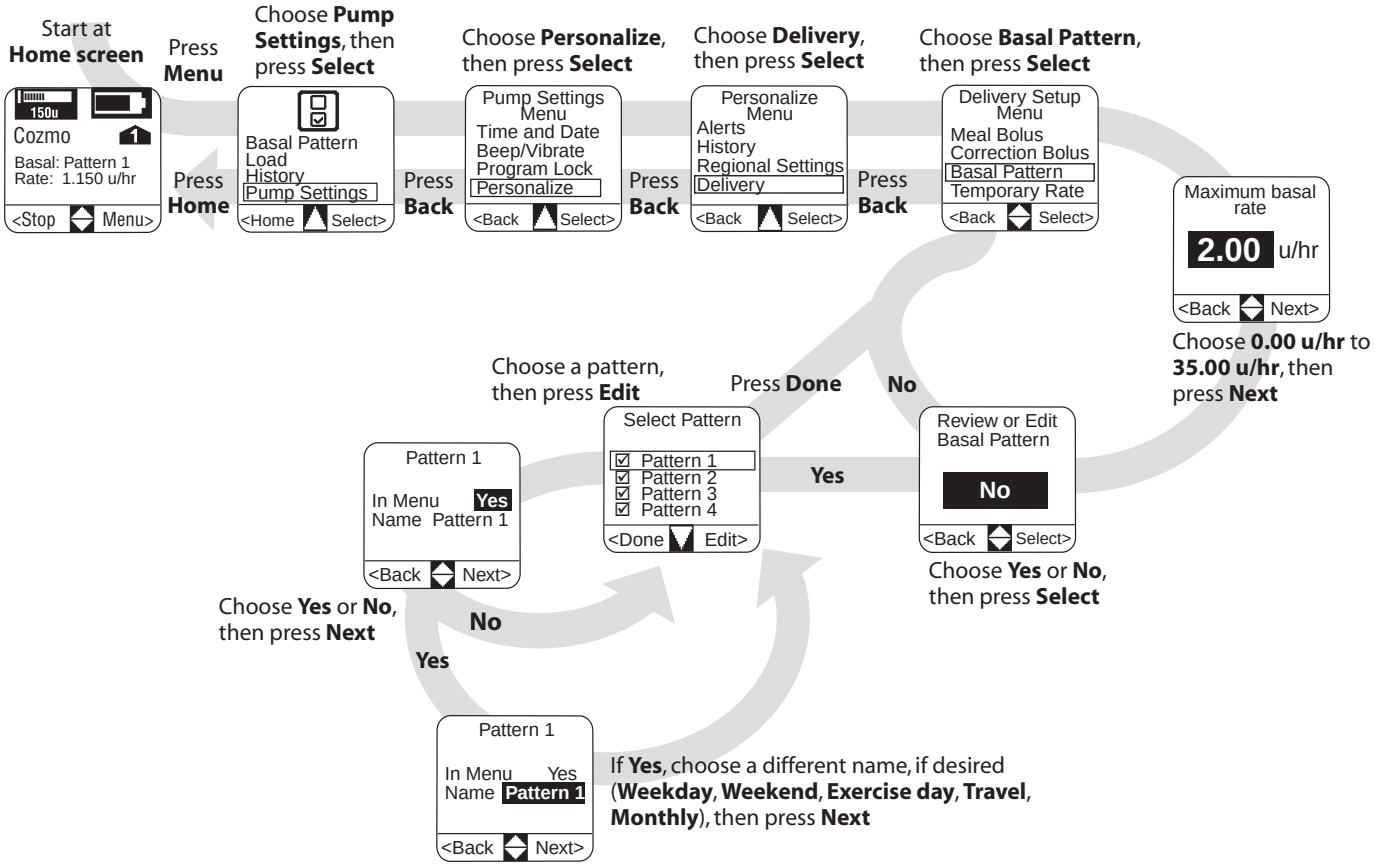
Basal patterns

☞ Warning: You should receive specific training on programming and using basal patterns. Please carefully read all instructions and talk to your health-care provider.

These settings should be programmed before you actually program (edit) the individual basal patterns.

The pump allows up to 4 basal patterns, each of which can contain up to 48 time/rate "segments." In this menu, you can choose which patterns you want displayed in Basal Pattern in the main menu, and also select a name for each pattern (included here is a list of preselected names; if you want to create a name, you will need to use My Treatment Assistant™).

Personalizing basal patterns



Editing basal patterns

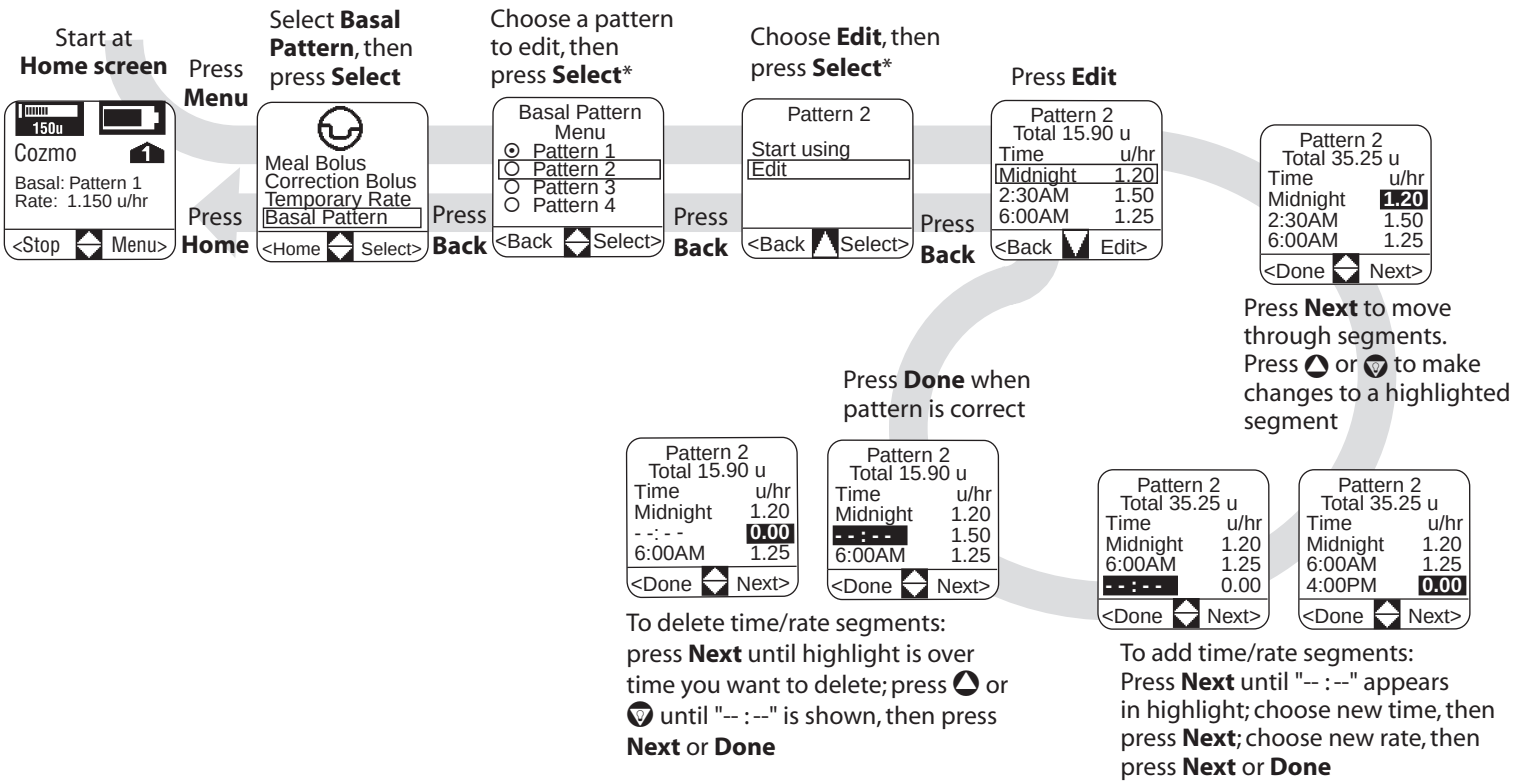
☞ Warning: It is vital to get the basal patterns correct. If a basal rate is too high or too low, all your insulin delivery throughout the day and night will be incorrect, including boluses.

☞ Warning: Many things can affect how your body uses insulin. To avoid problems, contact your healthcare provider before making big lifestyle changes, such as starting or stopping an intensive exercise program, or if you experience a significant weight loss or weight gain, etc. In these cases your basal rates may need to be modified.

Your healthcare provider will initially program, or help you as you program, your basal patterns. You may be asked to test your BG level multiple times over a period of a few days and chart the results to identify your insulin needs.

Continue to modify, add and delete segments until the pattern is correct. Instructions for using a pattern follow.

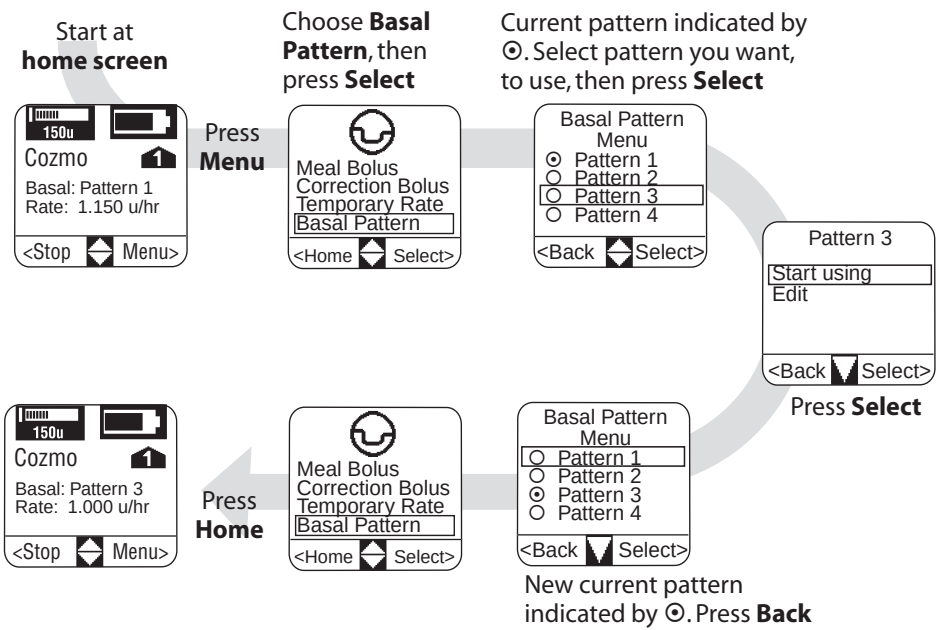
Editing basal patterns



*These screens only appear if more than 1 pattern is selected to display in the basal pattern menu.

Using basal patterns

Many of the screens in the Basal Pattern menu can be personalized by programming the pump or by using My Treatment Assistant™. If the screens on your pump have been personalized, they will be different than those shown here. It is also possible to program the pump to display only specified basal patterns. Talk to your healthcare provider about any personalization which was done to your pump. If you are currently running a Temporary Rate, starting a different basal pattern will cancel the remainder of the temporary program.



Notes:

What's In This Section?

Deltec CoZmo™

The Freedom to Be You.™

- About the alarms (beep/vibrate settings)
- Troubleshooting
  - Alarms
  - Alerts
  - Other Messages
- Cleaning your pump
- Servicing your pump
- Troubleshooting health problems
  - Low blood glucose
  - High blood glucose
  - Diabetic Ketoacidosis (DKA)
  - Skin infections
- Tips for sick days
  - Sick day plan
- Personal pump removal guidelines
- Your pump &
  - Extreme temperatures
  - Water
  - Contact sports
- Your basal rates, boluses &
  - Your weight
  - Your level of exercise
  - Your growth
  - Your mestrual period
  - Starting new medications/supplements
- If you drop your pump or hit it hard

About the alarms (Beep/Vibrate settings)

The pump can be set to "**Beep**" or **"Vibrate**" when an alert or alarm occurs (see chapter 2, page 27). With **Beep** selected, the pump beeps when you press a key. When **Vibrate** is selected, the pump will not beep (or vibrate) when keys are pressed. (**NOTE:** the battery is used much more quickly when you use **Vibrate**.)

There are several types of alarm tones/vibration patterns:

- **Continuous alarm:** Indicates a problem which caused insulin delivery to be stopped. Since the pump uses short-acting insulin, your BG level will start to rise very quickly. See to alarms immediately.

  Beep: 4 double-beeps, repeating every 10 seconds until you press the appropriate key to silence it.

  Vibrate: 4 double-vibrations, repeated every 10 seconds until you press the appropriate key to silence it.

- **Attention alarm:** Indicates a problem that you need to see to, however it is not serious enough to have stopped insulin delivery. Examples include low cartridge volume, low battery, etc.

  Beep: 4 double-beeps, repeated once per minute.

  Vibrate: 4 double-vibrations, repeated once per minute.

- **Single alarm:** This is a notification alert.

  Beep: pump beeps once.

  Vibrate: pump vibrates once.

- **Stopped alarm:** Indicates the pump is stopped.

  Beep: 3 beeps, repeated every 5 minutes.

  Vibrate: 3 vibrations, repeated every 5 minutes.

You can set the volume of the **Beep** alarm to **Low**, **Medium**, or **High** (see chapter 2, page 27). However, if you have selected **Low** or **Medium**, and a delivery-related alarm (or other alarm which affects delivery) occurs that is not cleared within 5 minutes, the pump will automatically select the **High** setting in order to get your attention.

Also, if **Vibrate** is selected and you do not clear the alarm within 5 minutes, the pump will automatically begin to switch between vibrating and beeping at the **High** setting.

The backlight automatically lights whenever an alarm or alert occurs.

Troubleshooting

Alarms

Message in display	What it means / Alarm	How to make it stop
Battery depleted Delivery stopped Insert a new battery	Delivery stops. The battery does not have enough power for the pump to work. Continuous alarm; or, if power is too low, 2 beeps repeated continuously.	You must change the battery immediately. If the repeating 2 beep alarm occurs, power may be so low that the display goes blank or the pump continually attempts to restart; always replace the battery whenever this occurs.
Blockage detected No delivery. Check tubing or site for blockage	Delivery stops. There is something preventing insulin from being delivered. Continuous alarm.	Press OK to silence alarm and stop delivery. Alarm will continue to occur until blockage is cleared. Disconnect your infusion set from the access device until the blockage is cleared. Check tubing, making sure it is not kinked; make sure tubing is not trapped in clothing or pouch. Check access site, making sure access device is properly inserted. If still blocked, change access device, infusion set, and access site. Test your BG level. Restart delivery.
Cartridge empty Insert filled cartridge to continue delivery	Delivery stops. The cartridge is empty. Continuous alarm.	Press OK. You must load a new cartridge now.

Alarms - continued

Message in display	What it means / Alarm	How to make it stop
Cartridge removed Press OK to begin load process	Delivery stops. Pump detected that cartridge was removed or not properly installed. Continuous alarm.	Press OK. Disconnect the tubing from the access device. Correctly load a cartridge onto the pushrod and prime the tubing (see page 35).
Cartridge very low Basal is delivering No bolus allowed or bolus suspended	The cartridge is nearly empty. Basal delivery continues, but a bolus cannot be delivered. Continuous alarm.	Press OK. There is enough insulin to continue delivering the basal for a short time, but not enough to start a bolus, or complete a bolus that is in process (the bolus will be completed when a new cartridge is loaded). You must begin preparation to load a new cartridge.
Delivery Limit xxx units already delivered in past 60 min. Delivery is stopped	Delivery stops. You have attempted to deliver more insulin than is allowed in the last hour (see Delivery Limit, page 28). Continuous alarm.	Press OK. Check your BG level immediately. Contact your healthcare provider if you are unable to maintain your target BG level. Increase the Delivery Limit alert, if indicated by your healthcare provider.
Key stuck Release key or remove battery	A key has been pressed continuously for 5 minutes, or a key was pressed during the pump's power up. Continuous alarm.	If you are pressing a key, stop pressing it. If you are not pressing a key, remove and reload the battery. If the alarm persists, there may be a problem with the keypad that requires service.
System fault Call for service	Delivery stops. The pump's computer has detected a problem with the pump. Continuous alarm.	Disconnect the tubing from the access device. Remove the battery to silence the alarm and contact Deltec, Inc. to initiate pump service. Do not use the pump. You must be prepared to inject insulin until a replacement pump arrives.

Alarms - continued

Message in display	What it means / Alarm	How to make it stop
No key pressed in xx:xx hours. Pump will stop and alarm in 30 seconds	Delivery will stop in 30 seconds unless you press Cancel. Attention alarm.	Press Cancel. This is the notification of the Automatic Off alarm. If you do not press Cancel, the pump will activate the Automatic Off alarm in 30 seconds.
This is an insulin pump Pump is stopped Medical help may be required *	This is the Automatic Off alarm. Continuous alarm.	If you are able, press OK. This indicates that no keys or buttons were pressed for an extended period (you select the interval when setting the feature). If you don't want to use the Automatic Off feature, you can turn it off (see page 28).

*Using the Treatment Assistant™ PC Communications System, you can create your own custom message for this alarm. If the screen has been customized, the message will be different than the one shown above.

Alerts

Message in display	What it means / Alarm	How to make it stop
Battery low Change battery soon	This alert occurs only during waking hours (6:00AM to 10:00PM). A series of 4 Attention alarms given every 4 hours until battery is dead.	Press OK. Change the battery as soon as possible.
Bolus Interrupted Remaining Amount: x.xxu Duration: xx:xxhr Continue?	Your last bolus was interrupted. The amount not delivered (and remaining duration, if applicable) appear in the display. Attention alarm.	To deliver the rest of the bolus, press Yes. If you do not want to deliver the rest of the bolus, press No.

Alerts - continued

Message in display	What it means / Alarm	How to make it stop
Cartridge Volume Low Change cartridge soon	The amount of insulin left in the cartridge is low. Alert repeats at intervals until **Cartridge Very Low** alarm occurs. **Attention alarm.**	Press **OK**. Replace the cartridge as soon as practical.
Check blood glucose It has been x:xx hours since your last bolus or cartridge change	It is time to test your BG level to make sure it is within your target range. **Attention alert.**	Press **OK**. Perform BG testing. If it is within your target range, do nothing. See the high and low blood glucose sections in this chapter if your BG level is outside your target range.
Delivery is stopped	The pump is stopped, and no insulin is being delivered. **Stopped alarm.**	Press **OK**. Alert screen and alarm (beep or vibration) occur every 5 minutes until **Resume** is pressed to restart insulin delivery.
Delivery Limit No bolus xxx units already delivered in past 60 min. Bolus would exceed limit.	The bolus you attempted was not delivered as it would exceed the delivery limit. **Attention alert.**	Press **OK**. You must wait to deliver the bolus, or contact your healthcare provider to discuss your delivery limit.
Extended delivery in progress - No combo or extended bolus allowed	You attempted to enter the extended or combination bolus menu when an extended bolus is being delivered. Single alarm.	Press **OK**. Only 1 extended bolus can be delivered at a time. If you want to stop the current extended bolus, from the home screen press **Stop**, then choose the type of delivery you want to stop.

Alerts - continued

Message in display	What it means / Alarm	How to make it stop
Alert BG is below target or may drop below target. No bolus suggested.	The pump has calculated that the "Current Blood Glucose" you entered would result in a BG level below your target. No correction bolus will be suggested. Attention alarm.	Press OK. Due to "insulin on board" (from 1 or more previous boluses which are still affecting your BG level), the pump has calculated a 0 (zero) bolus at this time. Recheck your BG level and treat a low BG as instructed on page 67 and according to any instructions given to you by your healthcare provider.
Missed meal bolus No bolus delivered between xx:xx and xx:xx.	A missed meal bolus alert was programmed, and no bolus was delivered during the selected time interval. Attention alarm.	Press OK. If you have eaten and forgotten your bolus, check your BG level immediately. Deliver a bolus, if required.
No bolus allowed Bolus in progress.	You attempted to deliver a bolus while a bolus was delivering. Single alarm.	Press OK. Only 1 bolus can be delivered at a time.
No bolus allowed Cartridge volume is very low.	You attempted to deliver a bolus, but the cartridge volume is too low. Single alarm.	Press OK. Load a new cartridge, then deliver the bolus.
No bolus allowed Pump is stopped.	You attempted to deliver a bolus while the pump was stopped. Single alarm.	Press OK. Restart the pump, then deliver the bolus.

Alerts - continued

Message in display	What it means / Alarm	How to make it stop
Program Defaulted Setup of cartridge volume required With no cartridge present, press Next	All pump settings have been reset to the default values, and the cartridge volume needs to be rechecked to make sure it will be displayed correctly on the home screen. Attention alarm.	Remove the cartridge (if present), then press Next.
Program Defaulted Set time and date: XX:XX XX XX/XX/XX	The time and date settings in the program have been reset and must be reprogrammed. Attention alarm.	Press the ▲ or ▼ key to choose the currently highlighted setting, then press Next to move highlight to next setting. When time and date are correct, press Done.
Program Defaulted You must reprogram the pump	All pump settings have been reset to the default values. Attention alarm.	Press OK. Reprogram all pump settings.
Site change reminder x days since site changed Time for new site?	It is time to change your cartridge, infusion set and access site. Attention alarm.	Press OK. Follow the instructions for Loading the cartridge in chapter 3, starting on page 35).
Temporary Rate Complete	The pump was delivering a Temporary Rate, which is now completed. Attention alarm.	Press OK. Pump has returned to the normal basal pattern.

Other messages

Message in display	What it means / Alarm	How to make it stop
Temp. Rate Incomplete Remaining Duration: xx.xxhr Rate: xx.xxx% Continue?	Your pump was delivering a Temporary Rate when power was lost. **Attention Alarm.**	To continue delivering the temporary rate, press **Yes**. If you do not want to continue the temporary rate, press **No**.
All basal rates programmed to zero	The pump detected: during power up, all basal pattern rates are programmed to zero; or, you selected "Start using" for a pattern in which the rates are all zeros. **Single alarm.**	Press **OK**. If necessary, go to the Basal Pattern menu and program a basal pattern.
Bolus Active An extended or combination bolus is now delivering.	You have attempted to enter the combination or extended bolus menu while a bolus of this type is being delivered. **Single alarm.**	Press **OK** to continue running the bolus. To stop the bolus, press **Stop**, select the bolus you want to stop then press **Select**. Press **Yes**.
Edit not saved Editing was not saved because an alarm occurred	An alarm or alert occurred while you were programming/editing a value. **Single alarm.**	Press **OK**. Reprogram the value.

Messages - continued

Message in display	What it means / Alarm	How to make it stop
No cartridge detected Cartridge missing or overfilled. Install cartridge to confirm sensor	You have attempted to use the "Load" portion of the load cartridge menu, but no cartridge is detected. It may also mean that you filled the cartridge too full (more than 300 units). Single alarm.	If a cartridge is installed (and with the infusion set attached to the cartridge) press down gently on the cartridge to push excess insulin into the tubing. If a cartridge is not installed, install one. Press Confirm. If the cartridge sensor is not confirmed, you will need to have your pump serviced.
Not complete Additional programming of this feature is required	You have partially programmed a feature, but have not completed all required programming. Single alarm.	Press OK. If desired, re-enter the menu and completely program the feature.
Rate above maximum Pattern exceeds maximum rate. Change basal rate maximum?	You have tried to set a basal pattern to display in the menu that exceeds the basal rate maximum. Single alarm.	Press Cancel to cancel setting the pattern to display in the menu, or press Yes to return to the basal rate maximum screen and increase the maximum.
Temporary Rate active	The pump is running a temporary rate. Single alarm.	Press OK.
Temporary Rate Active Changing basal pattern will end remaining temporary rate	You have attempted to change the basal pattern while a temporary rate is active. Single alarm.	Press OK to cancel temporary rate and change basal pattern, or press Cancel to continue temporary rate and continue with current basal pattern.

Messages - continued

Message in display	What it means / Alarm	How to make it stop
Temporary Rate Active Editing basal pattern will end remaining temporary rate	You have attempted to edit a basal pattern while a temporary rate is active. Single alarm.	Press OK to cancel the temporary rate and edit basal pattern, or press Cancel to continue temporary rate.
Temporary Rate Active Editing method will end remaining temporary rate	You have attempted to change the temporary rate method (Percent or Units/Hr) while a temporary rate is running. Single alarm.	Press OK to cancel the temporary rate and change the temporary rate method, or press Cancel to continue temporary rate.
This basal pattern is in use and must be displayed in menu	You have attempted to set the basal pattern that is currently in use to not display in menu. Single alarm.	Press OK. You can only set a basal pattern that is not currently in use so that it does not display in the Basal Pattern menu.
This will result in a basal rate of 0.0 u/hr for specified time period	You have programmed a basal pattern that will result in a sequence with a rate of zero. Single alarm.	If you want the pattern to run as programmed, press OK. If you want to reprogram the pattern, press Edit.

Cleaning your pump

Routinely clean your pump to prevent buildup of dirt or dried fluids. Try to wipe spills off the pump right away to avoid a sticky buildup, which will be harder to wipe off later.

When cleaning your pump, **ONLY** use a sponge or soft cloth with a solution of warm water and a mild soap, such as liquid dish or hand soap.

☞ **Caution: Strong household cleaners and chemicals will damage the pump's outer shell** if applied directly or indirectly (if it is on your hands, for instance). Avoid the following in particular:

- Household cleaners (such as Formula 409®)
- Jewelry cleaner
- Petroleum-based products (such as gasoline and GooGone®)
- Products that contain high levels of D.E.E.T. (such as Deepwoods Off® insect repellent)

Make sure to clean inside the battery or cartridge compartment; moisten one end of a cotton swab (such as a Q-tip®) and gently clean inside the compartment. Use the dry end of the swab to dry the compartment.

☞ **Caution: Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your pump, as they can scratch, discolor or damage the pump's outer shell.** If the display is scratched, it may be difficult to read and you will need to have it replaced. If the outer shell is chipped or cracked, it will no longer be watertight and will require service.

☞ **Caution: Never use steam or very hot water (exceeding 120˚F [49˚C]) in an attempt to sterilize the pump. Never put your pump in the dishwasher.** Exposing the pump to these high temperatures could damage the pump's electronics and result in the need to service your pump.

Servicing your pump

Should your pump become damaged or broken, or if it is not working properly, you will need to call Deltec, Inc. to arrange to have the pump replaced.

Before contacting Deltec, please be sure that you know the pump serial number (located on the back of the pump), and are able to give a brief description of the problem.

In the USA & Canada, contact Deltec Customer Service at

1-800-826-9703
Fax: 1-800-209-2145

Customer Service will arrange for a replacement pump to be shipped to you.

☞ **Warning: You must be prepared to inject insulin with an insulin syringe or pen until the new pump arrives.** Contact your physician if you require supplies, such as a prescription for intermediate- or long-acting insulin and syringes.

Before sending the pump, make sure that you have a complete record of all your pump settings so that you can program the replacement pump correctly when it arrives.

☞ **Warning: You must not use the replacement pump until it is correctly personalized.**

Troubleshooting health problems

Low blood glucose (hypoglycemia)

Blood glucose lower than target. Signs and symptoms may include: shakiness, sweating, dizziness, cold or clammy skin, looking pale, tingling and numbness in hands or around lips, mood changes. Low blood glucose may lead to loss of consciousness. Some causes of low blood glucose include too much insulin given, increased activity/exercise, decreased food/meal frequency, and alcohol consumption.

Treatment: Immediately take 15 grams of fast-acting carbohydrate (preferably glucose tablets/gel; or juice or hard candy), and recheck in 15 minutes. If it is still very low (70 mg/dl [4 mmol/L] or lower) after 15 minutes, eat another 15 grams of carbohydrate and recheck in 15 minutes. Contact your healthcare provider as needed.

You must check your BG level at least 4 to 6 times per day (or as indicated by your healthcare provider) to be alerted to low BG levels.

If you have frequent low blood glucose, especially if at about the same time every day, talk to your healthcare provider. It may be necessary to change your basal rate, and/or adjust your bolus amounts.

High blood glucose (hyperglycemia)

Blood glucose level higher than target. Signs and symptoms include: increased thirst, frequent urination, blurred vision and high BG reading upon testing. See the table at right and on the following pages for some possible causes of high blood glucose.

Treatment: check your BG level immediately and, if required, deliver a Correction bolus. If very high (above 250 mg/dl [14 mmol/L]), check for ketones in your urine. Recheck your blood glucose in one hour following treatment. Contact your healthcare provider as needed.

Monitor BG level and for ketones closely. See Diabetic Ketoacidosis guidelines.

Problem	Corrective Action
Blockage (occlusion)	See Troubleshooting Pump Alarms, this chapter.
Increased food/ meal frequency	Deliver a Correction bolus to lower your BG level.
Decreased physical activity	Deliver a Correction bolus to lower your BG level.
Illness/stress	Deliver a Correction bolus to lower your BG level.
Expired/ineffective insulin	Change the insulin, cartridge and infusion set.
Not enough insulin given	Deliver a Correction bolus to lower your BG level.
Empty cartridge	Replace cartridge. If needed, deliver a Correction bolus.

Infusion Set and/or Access Site problems :

Problem	Corrective Action
Poor insulin absorption	Check access site for lumps, scarring or bruising (hypertrophied areas). Move the access site, if necessary.
Access site red, itchy, irritated; bumps or nodules at site	Deliver a Correction bolus to lower your BG level. Move the access site, if necessary.
Air bubbles in cartridge/infusion set or leaks at connections	Make sure all connections are tight and not leaking (wrap tissue around connectors to check for moisture). Look for air bubbles in cartridge and infusion set. Disconnect infusion set from your body and use the Fill tubing feature to remove large air bubbles, if needed.
Kinked tubing	Inspect entire length of infusion set for kinks, including the safety loop. Make sure your clothing and/or pump pouch are not pinching/restricting tubing. Change infusion set, if required.
Needle/cannula dislodged	If needle/cannula is dislodged, change infusion set and access site.

Diabetic Ketoacidosis (DKA)

A serious condition that occurs when there is not enough insulin to allow the glucose in the blood to be used by the cells in your body for energy. The cells begin to burn the body's stored fat reserves for fuel. Ketones are produced when fat is burned and these ketones change the chemistry of the body. Ketones can be detected using a blood or urine test. DKA can happen within a few hours when there is not enough insulin available, and can lead to unconsciousness and death. Signs and symptoms include: dry skin/tongue, nausea and/or vomiting, fruity odor to breath, shortness of breath, rapid pulse, rapid breathing, BG level over 300 mg/dl (17 mmol/L), unresponsiveness, coma.

Treatment: since some of the early symptoms may be explained as flu or food poisoning, it is vital to immediately test your BG level and urine for ketones. Treat the high blood glucose, and if moderate to high levels of ketones are present in your urine, follow the DKA corrective action plan from your your healthcare provider. Call your healthcare provider.

Checking your BG level regularly and properly treating high blood glucose (hyperglycemia) can help you avoid DKA.

My DKA plan

Skin infections

Skin infections may be experienced when using an insulin pump because the cannula or needle remains in place for 2 to 3 days. It is vital that proper aseptic technique be used. Signs and symptoms may include: redness, swelling, soreness, drainage, and/or the skin may feel warm to the touch

Treatment: immediately change your infusion set and access device, and switch to a new access site well away from the original site. Contact your healthcare provider.

Tips for sick days

During illnesses like colds and flu, controlling your BG level may be more difficult.

You can use the Temporary Rate program to increase or decrease your basal rate for the duration of your illness.

☞ **Warning: Never stop taking your insulin because of illness.** Even if you are too sick to eat, your body still needs insulin.

☞ **Warning: During an illness, check your BG level before mealtime and every 2 to 4 hours. Check your urine for ketones until you feel better.**

☞ **Warning: Even though you are sick, you still need fluids, calories and carbohydrates.** Drink 4 to 8 ounces of clear liquids containing sugar every 30 to 60 minutes.

Contact your healthcare provider whenever:

- Your BG level is higher than 250 mg/dl (14 mmol/L) after delivering a correction bolus
- Persistent or excessive nausea, vomiting and/or diarrhea lasts longer than 4 hours
- you have ketones in your urine

My sick day plan

Emergency supplies

Always have emergency supplies on hand. The supplies should include:

- emergency contact phone numbers
- medical ID (bracelet, etc.)
- blood glucose monitoring supplies
- urine ketone test strips
- glucose tablets, glucose gel or other source of fast-acting glucose (juice or hard candy)
- injectable short-acting insulin
- syringe(s) and needle(s), or an insulin pen
- wipes/swabs (I.V. Prep®, isopropyl alcohol, Betadine®, Hibiclens®, etc.)
- dressing and tape
- spare alkaline AAA (IEC LR03) batteries
- spare Deltec cartridge(s) and infusion set(s)

As always, discuss with your healthcare provider any special supplies you might need in your emergency kit.

Personal pump removal guidelines

Your pump &:

Extreme temperatures

Insulin in the cartridge can freeze if exposed to temperatures below 32˚F (0˚C) and can lose its potency. If you are outside in very cold temperatures for any length of time, keep the pump next to your body and covered by warm clothing.

Insulin can also lose its potency in very warm temperatures. Avoid leaving your pump in direct sunlight. Remove your pump before entering a hot tub, jacuzzi or sauna, as the temperatures may be too high for the pump to operate properly, and the insulin can start to lose its potency. See Specifications in the Technical Information chapter for appropriate storage and operation temperatures.

Water

As long as the pump's labels and outer shell are intact (no cracks or chips), the pump is watertight, so you do not have to remove the pump when showering or bathing, and can participate in unlimited swimming activities. When diving, the pump is watertight to a depth of 8 feet (2.4 meters) for 30 minutes or 12 feet (3.6 meters) for 3

minutes. Dry the pump off with a clean towel when you are finished. If swimming in salt water, rinse the pump in tap water and then dry it off with a clean towel to prevent a salt buildup on the pump's outer shell and display.

You must use a watertight dressing on your access site when entering the water.

Contact sports

When participating in sports, particularly contact sports, talk to your healthcare provider about whether you need to remove your pump. You will need to decide on an insulin plan during sports.

Your basal rates, boluses &:

Your weight

Your weight can have a significant effect on how your body uses insulin. If you experience a significant weight loss or weight gain, contact your healthcare provider. Your basal pattern(s) and boluses may need to be modified.

Your level of exercise

Exercise can have a significant effect on how your body uses insulin. When you are exercising, your body may need less insulin. If you plan on starting an exercise regimen (or discontinuing one), contact your healthcare provider. Your basal pattern(s) and boluses may need to be modified.

Your growth (children & teens)

Growth spurts and the onset of puberty can have a significant effect on blood glucose, which may significantly affect the required total daily insulin dose. If you or your child are experiencing problems maintaining the target BG level, contact your healthcare provider.

Your menstrual period

Many women see a change in their BG level right before their monthly period. If this occurs, contact your healthcare provider. They may want to designate one of the pump's 4 basal patterns specifically for your period, or they may want you to use the Temporary rate feature.

Starting new medications / supplements

Certain medications can have an effect on how your body uses insulin. This is particularly true with steroid medication like prednisone and cortisone. Always make sure that any physician prescribing medications to you knows about your diabetes. Then, contact your healthcare provider right away to decide if any modifications in your basal patterns or boluses are needed.

Herbal supplements may also have an effect on your health. Never begin taking any herbal supplement without first discussing it with your healthcare provider.

If you drop your pump or hit it hard

If you drop your pump or hit it against something hard, you will need to immediately look it over carefully to make sure it is not damaged. Disconnect your infusion set from your body and suspend delivery until you have made sure the pump is working correctly (see instructions provided with the infusion set for disconnecting). Remove the battery, then reinsert it. The pump will perform the self-tests, and let you know if there is a problem.

Make sure the pump display is working correctly. If there are missing or incomplete characters, you will need to have the pump serviced.

Look over the pump's outer shell carefully, checking for cracks or chips. If there are cracks or chips, the pump will no longer be watertight. You will need to have the pump serviced if there is any damage.

Make sure the cartridge cap and battery cap are in place and secure. Check all connections on the cartridge and infusion set (wrap a piece of tissue paper around the connections to check for moisture, which could indicate a leak). If moisture is present, tighten the connectors. If the connectors appear damaged, you must replace the cartridge and infusion set.

☞ **Warning: If you drop the pump or hit it against something hard, always inspect it carefully to make sure it is still working properly.** Make sure the display is working correctly, and the cartridge, cartridge cap, battery cap and infusion set are connected correctly. Wrap a piece of tissue paper around the connections to check for moisture (which could indicate a leak). If there is damage to the pump outer shell (cracks, chips), the pump may no longer be watertight.

☞ **Warning: If the display has missing or incomplete characters, or if the pump does not seem to be working correctly, stop using the pump immediately.** Contact your healthcare provider for health advice and Deltec, Inc. for information on servicing your pump. Be prepared to inject insulin with an insulin syringe or pen.

Notes:

What's In This Section?

Deltec CoZmo™

The Freedom to Be You.™

Programming and using these features
Correction bolus
- Personalizing the correction bolus
- Delivering a correction bolus

Touch bolus
- Making touch bolus available
- Delivering a touch bolus

Extended bolus
- Making extended bolus available
- Delivering an extended bolus
- Stopping an extended bolus

Combination bolus
- Making combination bolus available
- Delivering a combination bolus
- Stopping a combination bolus

Temporary rate
- Personalizing the temporary rate
- Using the temporary rate
- Stopping a temporary rate

Programming and using these features

☞ Warning: Programming and using the features described in this chapter includes information that may require a greater understanding of insulin pump therapy and should not be attempted without help from your healthcare provider.

☞ Warning: Programming many of these settings can only occur after testing and fine-tuning so that you get the best possible results from insulin pump therapy. You should receive specific training on programming and using the pump. Please carefully read all instructions and talk to your healthcare provider.

Correction Bolus

The Correction Bolus is designed to lower a high BG level. You determine where the correction bolus appears; in the main menu, as part of your meal bolus, both, or neither. You also select how you measure your blood glucose (in the USA, blood glucose is generally measured in mg/dl; outside the USA, blood glucose is generally measured in mmol/L).

Correction Bolus / 1 unit decreases BG

This setting is the amount your blood glucose drops for each unit of insulin delivered.

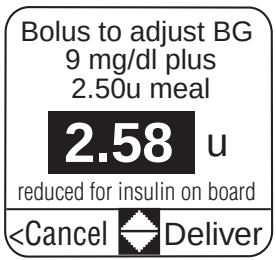
☞ Warning: Talk to your healthcare provider to determine your correction bolus factor.

Duration of insulin action

It takes your body a certain amount of time to fully use an insulin bolus. This setting looks at previously delivered boluses and determines, based on the amount of time you have programmed here, if any of that previous bolus is still actively affecting your BG level.

☞ Warning: Talk to your healthcare provider to determine your duration of insulin action.

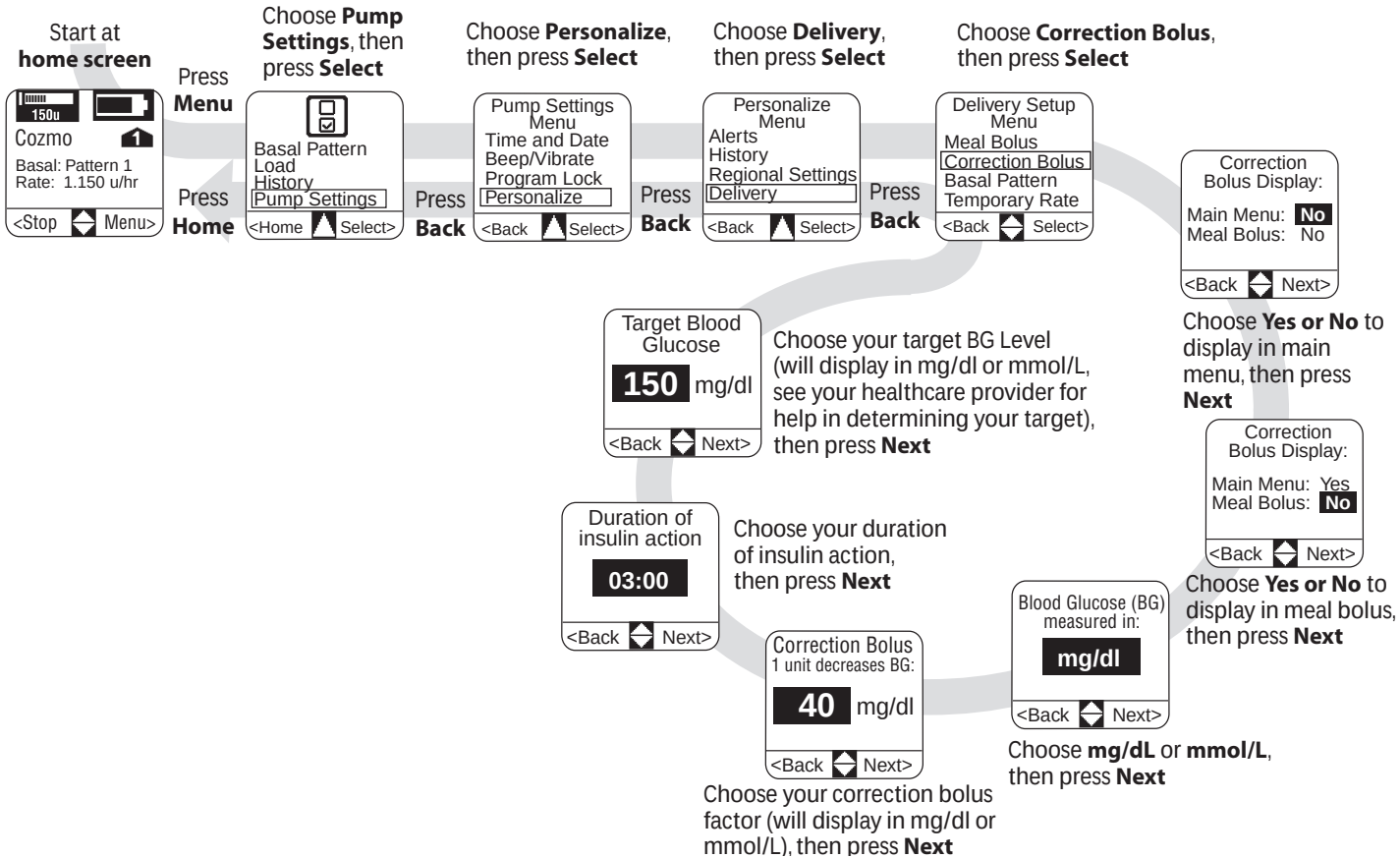
Once your duration of insulin action is correctly programmed, when you use the correction bolus feature any still active insulin in your body from a previous bolus will be taken into consideration and the screen that tells you the bolus amount recommended shows that the amount was reduced due to this “insulin on-board.”



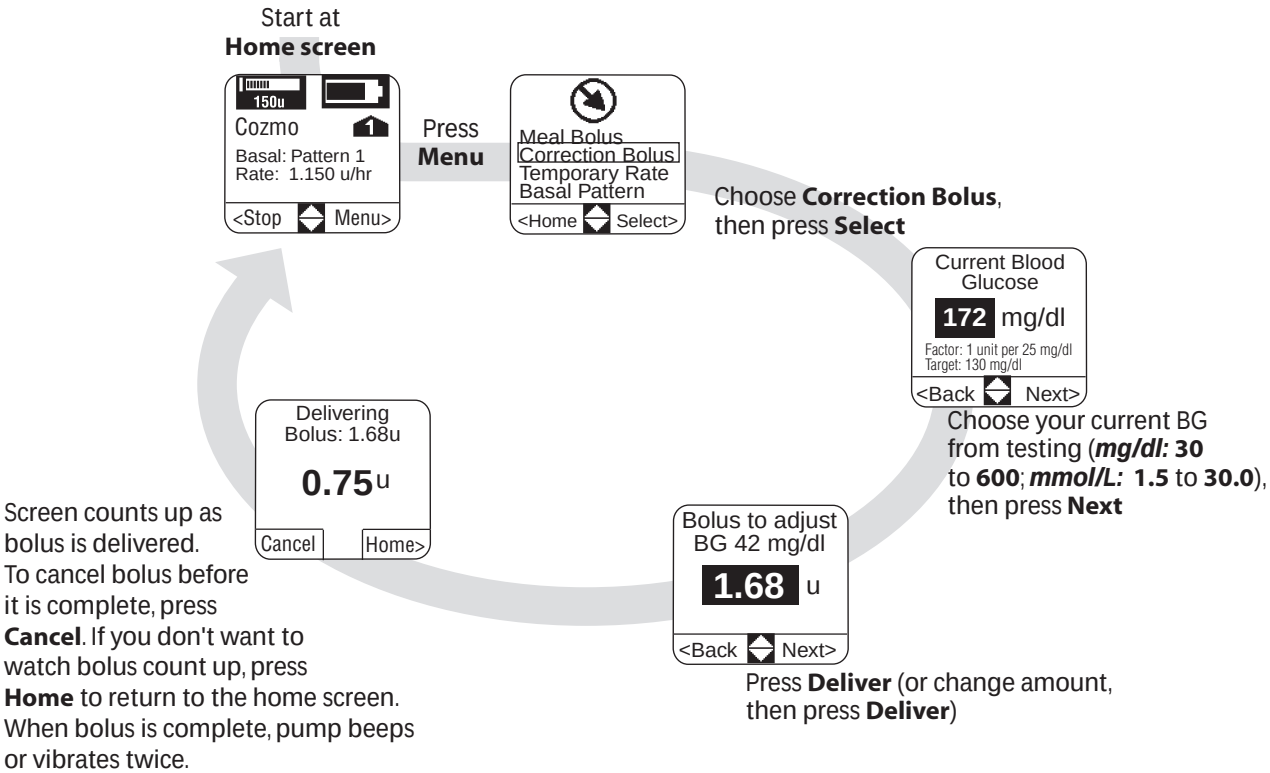
Target Blood Glucose

You will work with your healthcare provider to determine a target blood glucose level specifically for you.

Personalizing the correction bolus



Delivering a correction bolus (main menu*)


Start at
Home screen
150u
Cozmo
Basal: Pattern 1
Rate: 1.150 u/hr
<Stop Menu>
Press
Menu
Meal Bolus
Correction Bolus
Temporary Rate
Basal Pattern
<Home Select>
Choose Correction Bolus, then press Select
Current Blood Glucose
172 mg/dl
Factor: 1 unit per 25 mg/dl
Target: 130 mg/dl
<Back Next>
Choose your current BG from testing (mg/dl: 30 to 600; mmol/L: 1.5 to 30.0), then press Next
Bolus to adjust BG 42 mg/dl
1.68 u
<Back Next>
Press Deliver (or change amount, then press Deliver)
Delivering Bolus: 1.68u
0.75u
Cancel Home>
Screen counts up as bolus is delivered. To cancel bolus before it is complete, press Cancel. If you don't want to watch bolus count up, press Home to return to the home screen. When bolus is complete, pump beeps or vibrates twice.

*Delivering a correction bolus with a meal bolus is discussed in the meal bolus (meal bolus, extended bolus and combination bolus) chapters of this manual.

Touch Bolus

The Touch Bolus feature allows you to bypass the menu when delivering a meal bolus. It is called the Touch Bolus since you can program and deliver a bolus using sound or vibrations, without having to look at the pump's screen. The Touch Bolus button, on the side of the pump, is pressed to activate and use Touch Bolus. All of your programmed meal bolus settings (bolus type [Grams - Carb or Units - Insulin], maximum bolus and increment setting - see Meal Bolus in Using the Pump - Basics starting on page 44) will be used in Touch Bolus as well.

NOTE: Because Touch Bolus uses sound or vibration to count the size of a bolus, you are limited to a bolus of 24 increments (i.e., press once to activate, 24 presses maximum for bolus size, press and hold to deliver). If you want to deliver a very large bolus (which would require more than 24 presses), you must use the Meal Bolus menu to program and deliver the bolus.

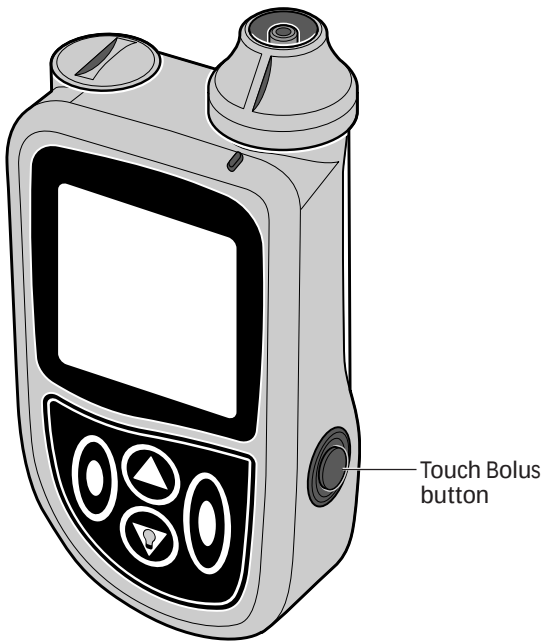
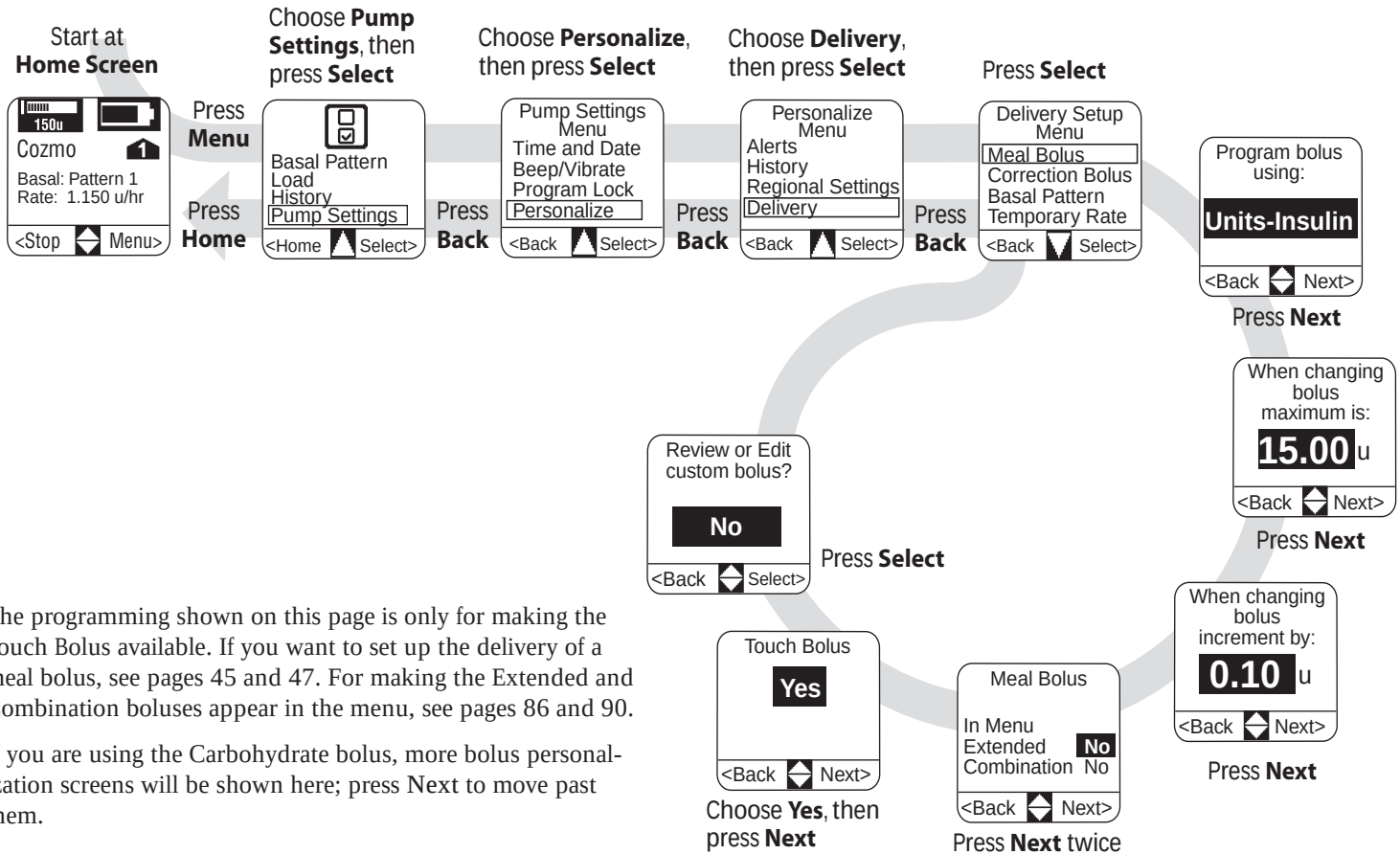


Figure 15

Making Touch Bolus available



The programming shown on this page is only for making the Touch Bolus available. If you want to set up the delivery of a meal bolus, see pages 45 and 47. For making the Extended and Combination boluses appear in the menu, see pages 86 and 90.

If you are using the Carbohydrate bolus, more bolus personalization screens will be shown here; press Next to move past them.

Delivering a Touch Bolus

Delivering a Touch Bolus is performed by pressing the Touch Bolus button on the side of the pump. A Touch Bolus can only be initiated when the pump is at the screensaver or home screen. The first press of the button causes the pump to beep or vibrate twice to indicate you are now ready to program and deliver a touch bolus. Then, each press of the button will adjust the size of the bolus by a predefined increment.

☞ Warning: When you first start using this feature, you should always take the pump out so you can view the screens as you program them. Then, once you are comfortable with how it works, you can program and deliver a bolus without even taking the pump out.

Whichever method you use to program a bolus (Grams - Carb or Units - Insulin) will be used here, too. Also, the increment amount you use (see When changing carbohydrates increment by: and/or When changing bolus increment by: screen(s) starting on page 44) will be used here.

For example: you use Grams - Carb, and your carbs increment by 5 grams. You are going to have a meal which consists of 25 grams of carbohydrate.

1. Press the Touch Bolus button once to activate the touch bolus (2 beeps or 2 vibrations).

NOTE: If you press and hold the button for longer than 2 seconds, the pump will automatically return to the home screen.

2. Then, within 10 seconds, press the Touch Bolus button 5 times (for 25 grams of carbohydrate).

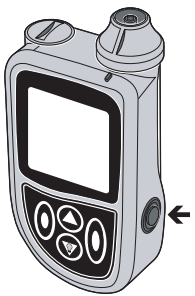
NOTE: If you press and hold the button for longer than 2 seconds, the pump will automatically return to the home screen.

The pump beeps 5 times (see scale shown below - the scale is designed to make it easier to keep count of the beeps) or vibrates 5 times.

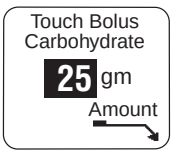
(Beep Beep Beep Beep Beep)

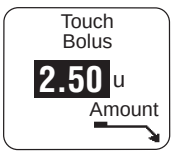
3. There will then be a pause, followed by 5 beeps (see scale above) or 5 vibrations to confirm the amount you have entered. If you hear more or less than 5 beeps or feel more or less than 5 vibrations, wait 10 seconds for the bolus to cancel, then begin at step 1, being careful to press the Touch Bolus button only the number of times indicated.

4. When the number of beeps or vibrations is correct, press *and hold* the Touch Bolus button until it beeps or vibrates once (to indicate delivery has started and you can let go of the button). After the bolus delivers, the pump returns to the home screen and beeps or vibrates twice to indicate that the bolus is complete.

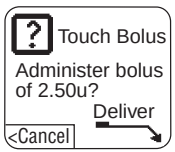


Press Touch Bolus button once (2 beeps or 2 vibrations); amount screen appears

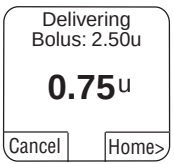




Press button to program amount (24 presses maximum, programmed in either grams of carbs or units of insulin) - a beep or vibration accompanies each button press



Listen for confirmation beeps/vibrations - one for each time you pressed the button. If amount is correct, press ***and hold*** Touch Bolus button until pump beeps or vibrates once (to indicate bolus delivery has started); if incorrect, press **Cancel** (or wait 10 seconds for screen to clear), then program correct amount



Screen counts up as bolus is delivered. (Press **Cancel** to stop bolus before it is complete.) Once bolus delivery is complete, pump returns to home screen and beeps or vibrates twice to indicate bolus is complete.

Extended Bolus

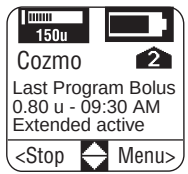
Some meals release glucose into the bloodstream slowly. The extended bolus is designed to deliver the bolus of insulin over this extended period. The extended bolus can be used when you eat a high protein or high fat meal, when you eat over a prolonged period (such as at a banquet), or if you have gastroparesis.

NOTE: Once you press Deliver to begin delivering an extended bolus, the pump will wait until the next "3 minute" interval (for example 12:00, 12:03, 12:06, etc.).

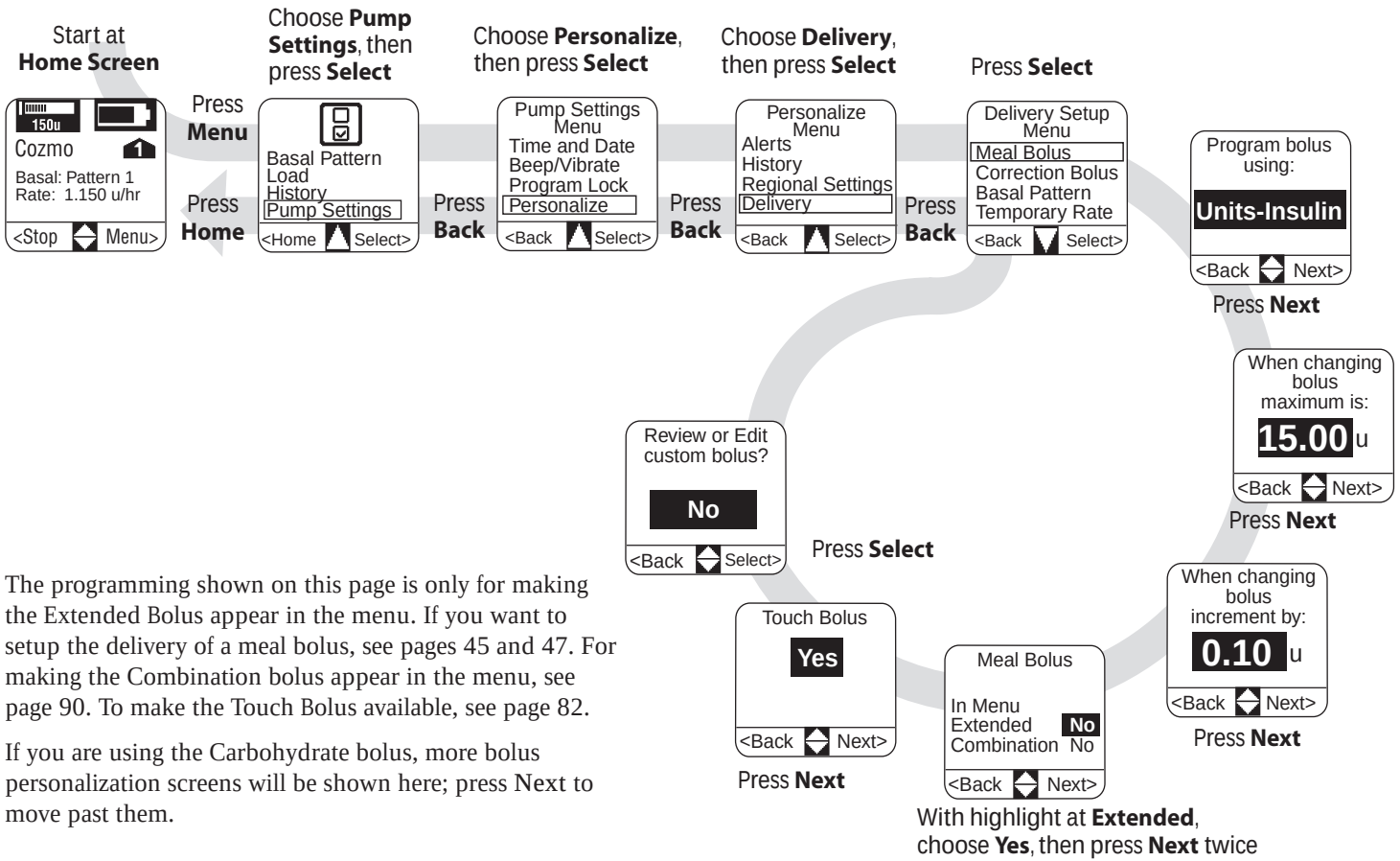
All of your programmed meal bolus settings (bolus type [Grams - Carb or Units - Insulin], maximum bolus and increment settings - see Meal Bolus in Using the Pump - Basics starting on page 44) will be used in the extended bolus as well.

☞ Warning: To use this feature, you will need to determine the length of time it takes your body to begin using these types of meals as blood glucose. Talk to your healthcare provider before attempting to use this feature.

When an extended bolus is in use, page 2 of the home screen will show that it is active.



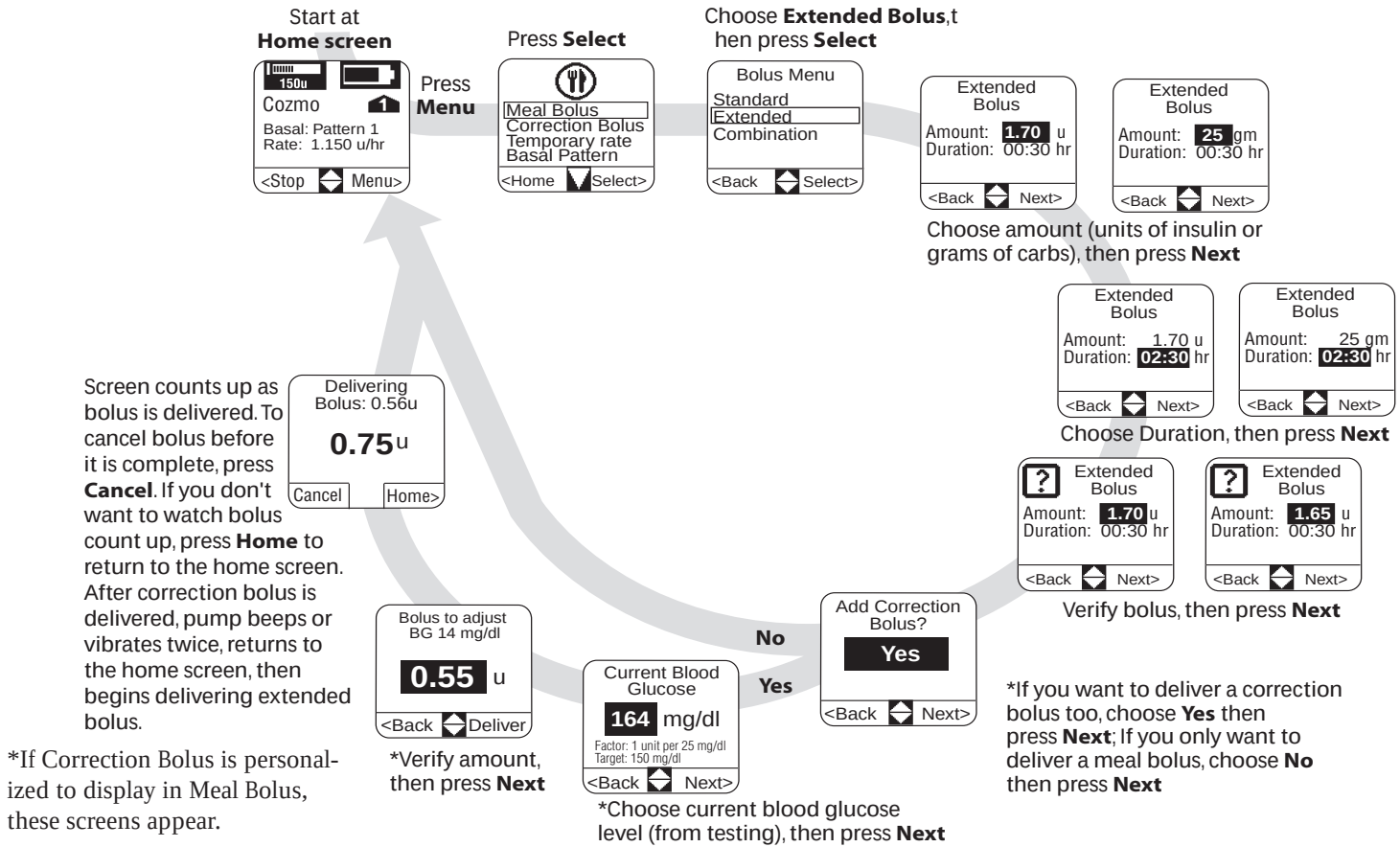
Personalizing the extended bolus



The programming shown on this page is only for making the Extended Bolus appear in the menu. If you want to setup the delivery of a meal bolus, see pages 45 and 47. For making the Combination bolus appear in the menu, see page 90. To make the Touch Bolus available, see page 82.

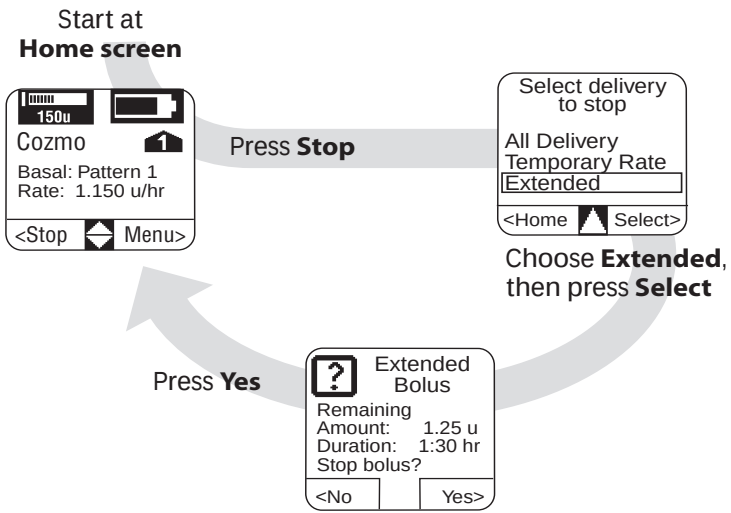
If you are using the Carbohydrate bolus, more bolus personalization screens will be shown here; press Next to move past them.

Delivering an extended bolus



*If Correction Bolus is personalized to display in Meal Bolus, these screens appear.

Stopping an extended bolus



Combination Bolus

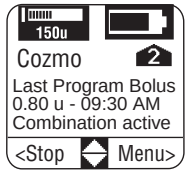
The combination bolus combines the features of the standard and extended bolus, which can be used when your meal consists of both rapidly and slowly absorbed carbohydrates, such as pizza. You program a percentage of the bolus to be delivered immediately, then the remainder over a programmed period of time.

NOTE: Once you press Deliver to begin delivering a combination bolus, the pump will wait until the next "3 minute" interval (for example 12:00, 12:03, 12:06, etc.).

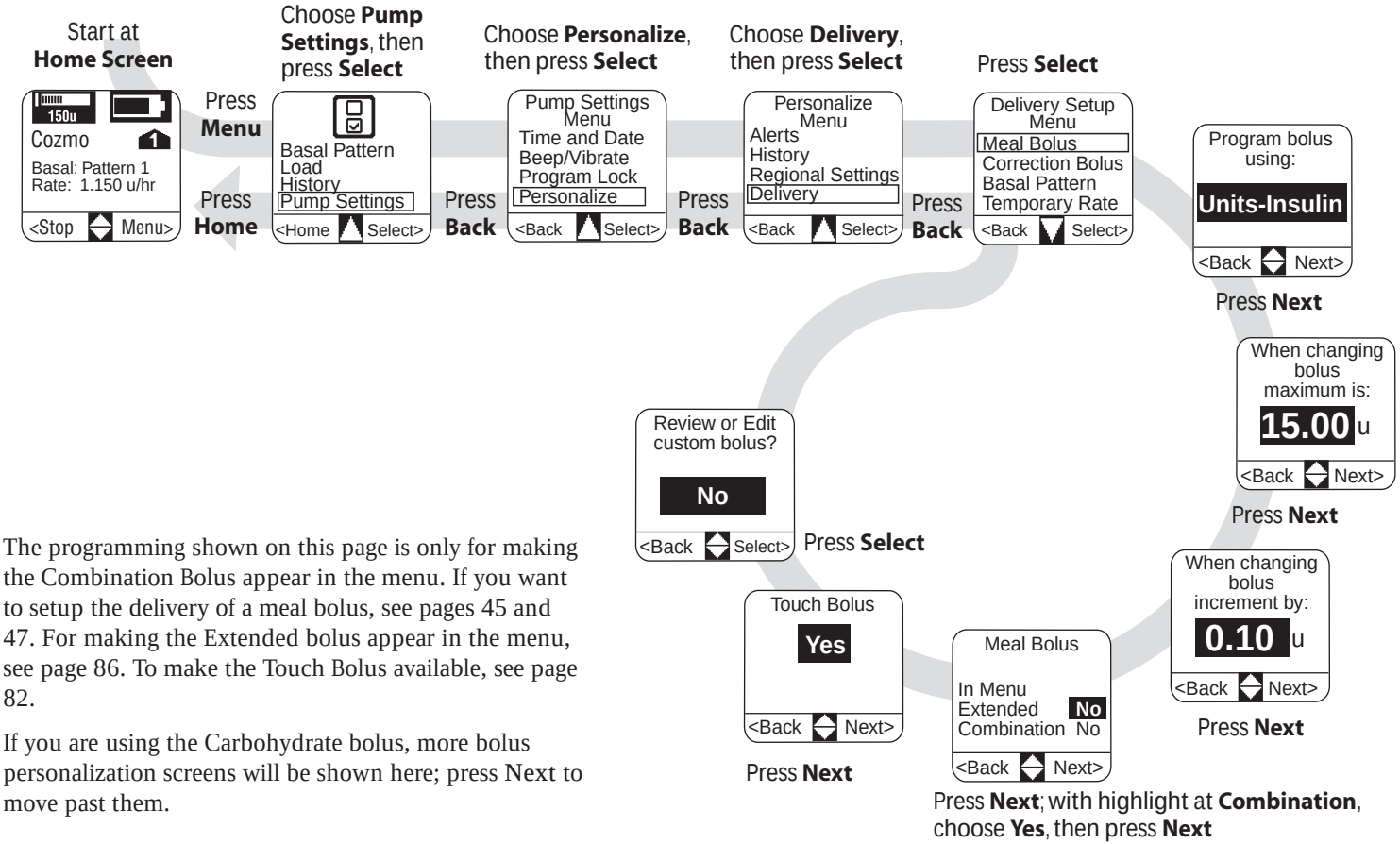
All of your programmed meal bolus settings (bolus type [Grams - Carb or Units - Insulin], maximum bolus and increment setting - see Meal Bolus in Using the Pump - Basics, starting on page 44) will be used in the combination bolus as well.

☞ Warning: To use this feature, you will need to determine the length of time it takes your body to begin using these types of meals as blood glucose. Talk to your healthcare provider before attempting to use this feature.

When a combination bolus is in use, page 2 of the home screen will show that it is active.



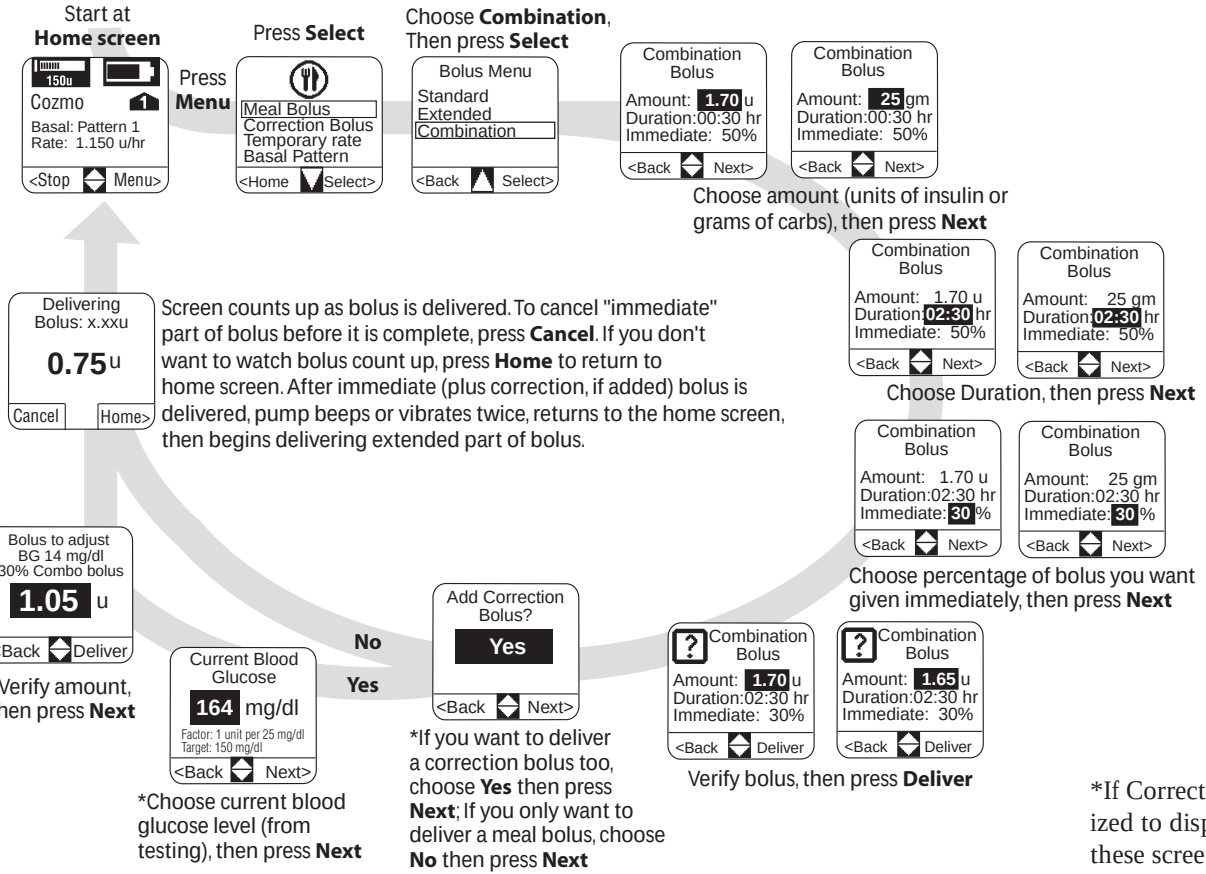
Personalizing the combination bolus



The programming shown on this page is only for making the Combination Bolus appear in the menu. If you want to setup the delivery of a meal bolus, see pages 45 and 47. For making the Extended bolus appear in the menu, see page 86. To make the Touch Bolus available, see page 82.

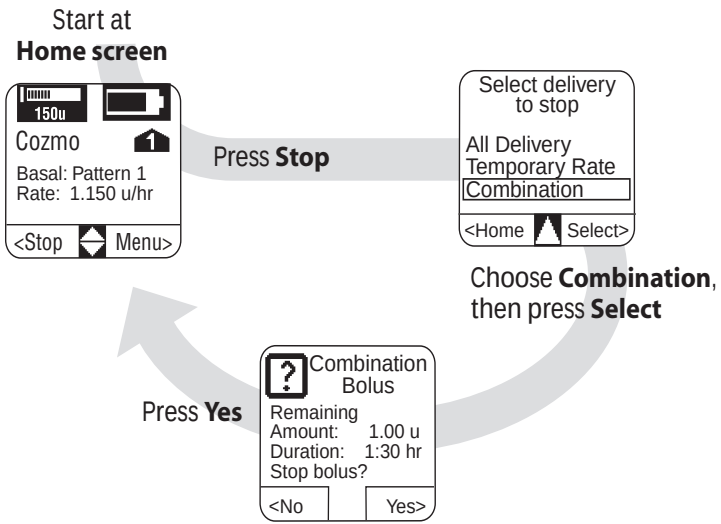
If you are using the Carbohydrate bolus, more bolus personalization screens will be shown here; press Next to move past them.

Delivering a combination bolus



*If Correction Bolus is personalized to display in Meal Bolus, these screens appear.

Stopping a combination bolus



Temporary Rate

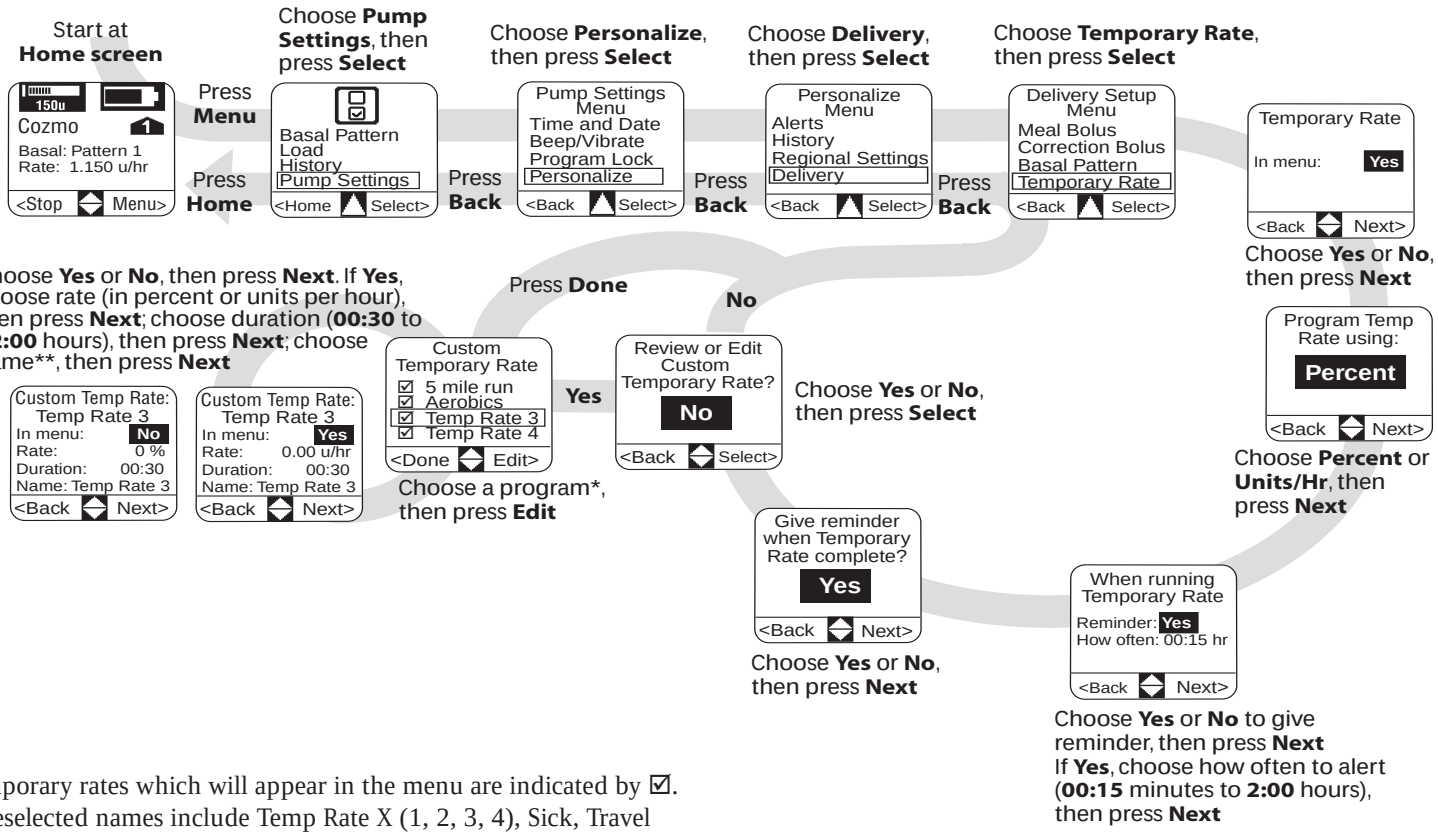
Temporary Rate allows you to temporarily raise or lower your basal rate. This feature can be useful when you need less insulin (for example, during exercise), or when you need more insulin (for example, when you are sick).

☞ Warning: Discuss your individual insulin needs with your healthcare provider.

You can program a temporary rate using “Percent” or “Units/Hr.” If you choose Percent, on the pump you will enter the percentage of the active rate that you want the pump to increase or decrease to. If your basal pattern has multiple rate segments, you may want to use percent, as it will monitor the pattern for changes, and continue to calculate the percent of the *active* rate. If you choose Units/Hr, on the pump you will enter a rate which the pump will deliver at for the duration of the temporary rate.

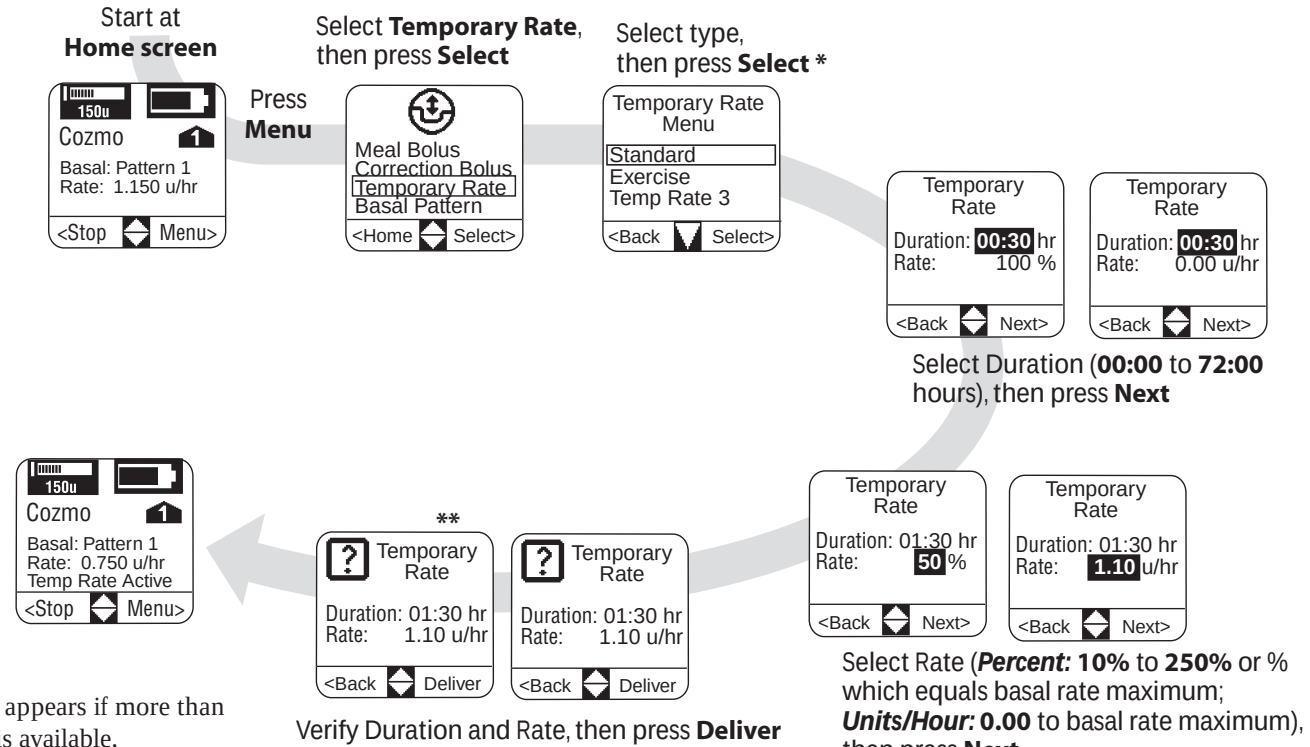
In this menu, you can also set up customized temporary rates, choose which ones you want displayed in the Temporary Rate menu, and also choose a name for each rate (from the preselected list. If you want to create a name, you will need to use My Treatment Assistant™).

Personalizing the temporary rate



*Temporary rates which will appear in the menu are indicated by ☑.
**Preselected names include Temp Rate X (1, 2, 3, 4), Sick, Travel and Exercise.

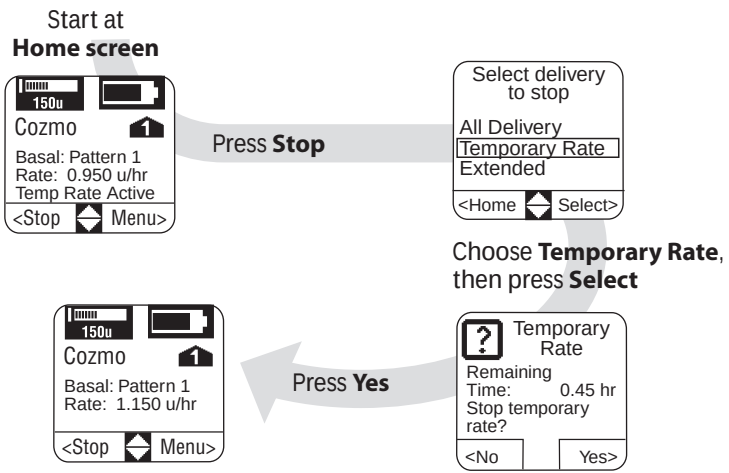
Using the temporary rate



*This screen only appears if more than 1 temporary rate is available.

**If running a custom temporary rate, the custom name is shown at the top of this screen.

Stopping a temporary rate



Notes:

Notes:

What's In This Section?

The Freedom to Be You.™

History
- Personalizing history
- Viewing history on the pump

Communications
- My Treatment Assistant™ PC Communications System

History

The pump stores history in 2 ways:

- by the delivery date; the pump stores delivery information for the previous 90 days
- as events; the pump stores information for the previous 2000 events.

History can be viewed directly on the pump screen, as well as using My Treatment Assistant™ PC Communications System.

You can program the pump so that individual history reports are not displayed (although the pump continues to keep track of this information), or can be viewed in History in the main menu. Note that if you have chosen not to display any of the history reports, History will not appear in the main menu.

Most history can be viewed in 2 ways;

1. As the actual events. The pump stores the information for the previous 90 days. You can scroll through these daily history reports using the ▲ and ▼ keys in History.
2. As an Average. In this method, the pump reviews the daily total for a number of days (you specify 2 to 30 days), and calculates an average.

The available history reports are:

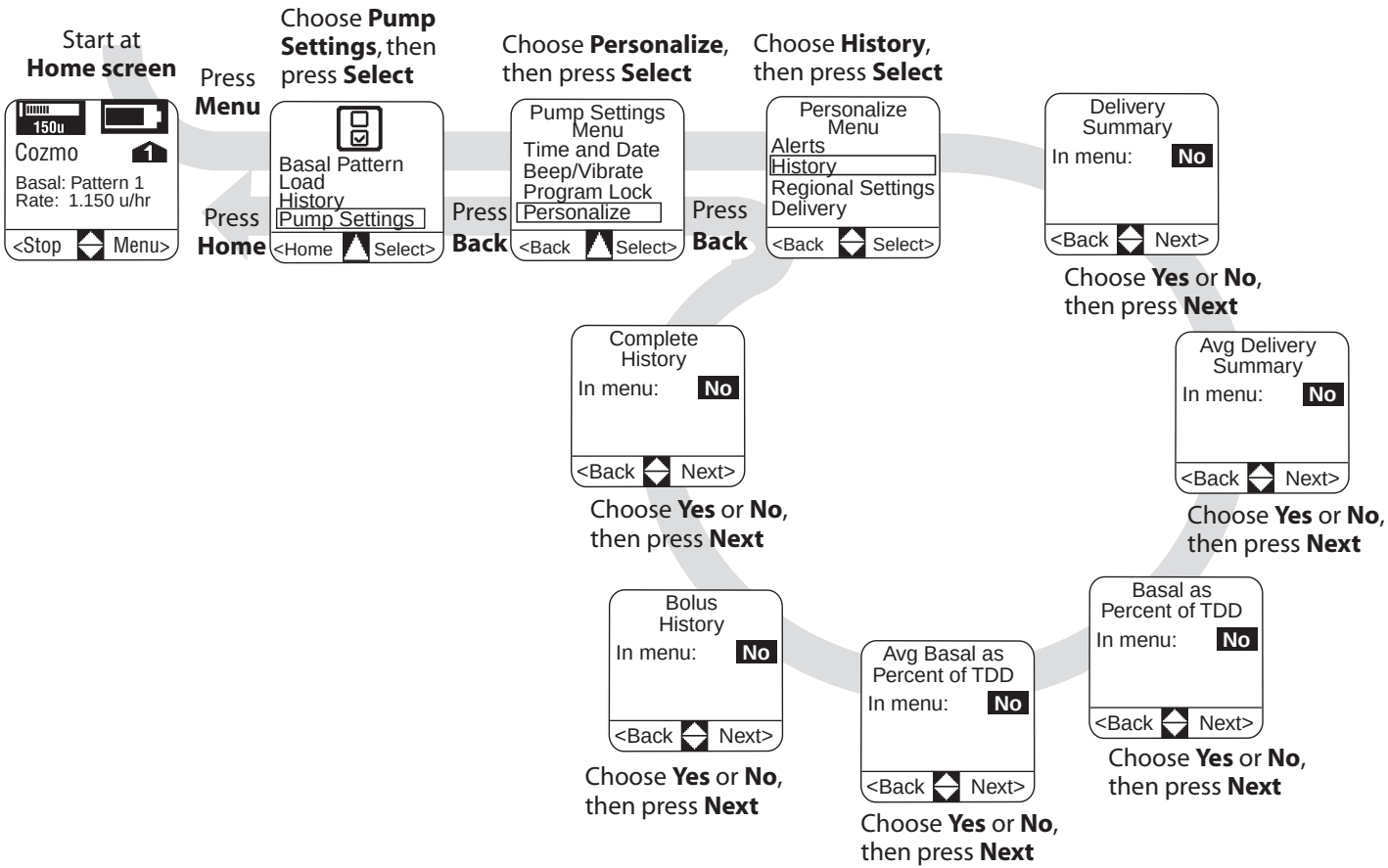
Delivery Summary & Average Delivery Summary: this is a daily breakdown of insulin delivery, and includes the daily total, meal bolus, carbs (if in use), correction bolus, and basal amounts. The average looks at these totals over a number of days (2 to 30), and calculates an average.

Basal as Percent of TDD (Total Daily Dose) & Average Basal as Percent of TDD: this shows what percent of the total amount of insulin delivered each day is basal insulin. The average looks at this percentage over a number of days (2 to 30), and calculates an average.

Bolus History: this shows the date, time and amount, both meal and correction, of all boluses currently contained in the "Complete History" report.

Complete History: this includes delivery totals, alerts, errors, battery changes, cartridge changes, changes to the pump program, etc. Each "event" in the complete history report includes the date and time of it's occurrence. It includes the last 2000 events.

Personalizing history

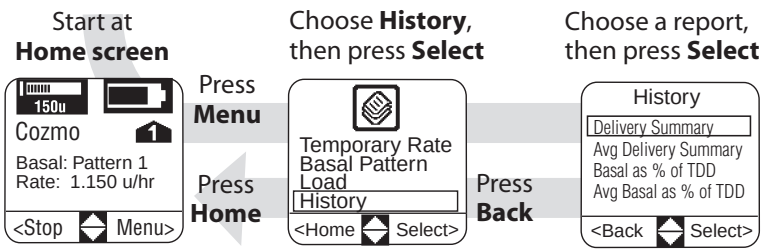


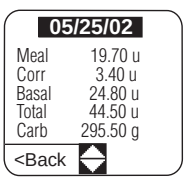
Viewing history on the pump

Once the reports are set to display in the menu, you can view them as part of History in the main menu.

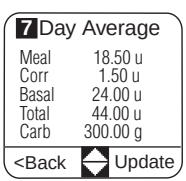
When your pump is new, you must allow enough time for the pump to accumulate data. For instance, if you try to view the "Basal as Percent of TDD" report before your pump has been in use for 1 full day, a screen appears that states "Not enough data to display report." You must wait until there is enough data stored in history.

To view reports in History, select the history report you want to view, then press Select. You can then move through the various reports by pressing the ▲ or ▼ keys.





A sample report screen. You can press the ▲ or ▼ keys to change the date so you can view other daily reports. Press **Back** when you're finished viewing the report.



A sample Average screen. Press the ▲ or ▼ key to change how many days you want the pump to look at when calculating the average (**2** to **30**), then press **Update** to see the new average. Press **Back** when you're finished viewing the report.

Communications

My Treatment Assistant™ PC Communications System

My Treatment Assistant™ is a Microsoft® Windows®-based program that allows the pump to communicate with a computer. My Treatment Assistant™ consists of 3 parts:

- **Personalize** - personalize is set up like the pump menu. You can perform all of the programming that you can do on the pump, plus:
  - you can create custom names for Basal Patterns;
  - you can create custom Meal Boluses (up to 12), and create names for each of these boluses;
  - you can create custom Temporary Rates (up to 8), and create names for each of these rates;
  - customize certain screens and information on the home screen;
  - create a customized message that will display should the Automatic Off alarm occur.

You can perform all of the pump programming tasks in My Treatment Assistant™, then send it to the pump. Or, if you want to keep a written record of your pump's program, you can download the pump's program into the computer and save, print and/or e-mail the entire pump program.

- **History** - you can view, save, print and/or e-mail all of the reports in history.
- **Configure** - used to configure My Treatment Assistant™. You decide whether you want access to be password controlled (you must create a password), whether you want general instructions to be displayed during start-up of the program, and whether you want the program to offer to print the pump's program when you get it from or send it to the pump.

Other features

"Help" is displayed right on the screen, and help for a specific task can be viewed by pressing the **?** icon near the group box.

Functions such as getting information from the pump, delivering information to the pump, saving, and e-mailing are performed by clicking buttons.

For specific information on installing My Treatment Assistant™ on your computer and connecting your pump to the computer, please see the *Getting Started* booklet supplied with My Treatment Assistant™.

In order for the pump to communicate with a computer, your computer must have an IR adapter.

Notes:

What's In This Section?

Deltec CoZmo™

The Freedom to Be You.™

Pump development standards
Pump specifications
Description of pump safety systems
Inspecting the pump

Pump development standards

AAMI ID26: 1998 - Medical Electrical Equipment — Part 2: Particular requirements for the safety of infusion pumps and controllers

ANSI/AAMI HE48: 1993 - Recommended Practice — Human factors engineering guidelines and preferred practices for the design of medical devices. (February 5, 1988 version) Design guideline.

ENV 50204 (1995) - Radiated electromagnetic field from digital radio telephone — Immunity test

IEC 60601-1 (Second Edition, 1988) - Medical Electrical Equipment, Part 1: General requirements for safety. Amendment 1 (1991), Amendment 2 (1995)

IEC 60601-1-1 (Second Edition, 1992) - Medical Electrical Equipment, Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems. Amendment 1 (1995)

IEC 60601-1-2 (1993) - General Requirements for Safety, Part 2 — Electromagnetic compatibility — Requirements and tests. (European Harmonized Standard)

IEC 60601-1-2 (2nd Edition, 01 June 1996, Committee Draft) - Medical Electrical Equipment, Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility — Requirements and tests

IEC 60601-1-4 (1996) - Medical Electrical Equipment, Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems

IEC 60601-2-24 (1998-02) - Medical Electrical Equipment, Part 2–24: Particular requirements for safety of infusion pumps and controllers

IEC 878 (First Edition, 1988) - Graphical symbols for electrical equipment in medical practice

IEC 61000-4-2 (1995) - Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques. Section 2: Electrostatic Discharge immunity test. Basic EMC Publication.

IEC 61000-4-3 (1995) - Electromagnetic Compatibility (EMC, Part 4: Testing and measurement techniques. Section 3: Radiated, radio frequency, electromagnetic fields immunity test. Basic EMC Publication. Amendment 1 (1998-06)

IEC 61000-4-8 (1993) - Electromagnetic Compatibility (EMC), Part 4: Testing and measurement techniques, Section 8: Power frequency magnetic field immunity test, 1993

CISPR11 (1990) - Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment. Amend-

ment 1 (1996; Amendment 2 (1996)

CISPR14 (1993) - International Special Committee on Radio Interference, limits and methods of measurement of radio interference characteristics of household electrical appliances, portable tools and similar electrical apparatus. Amendment 1 (1996)

IEC 529 - Degrees of protection provided by enclosures (IP Code)

RTCA/DO-160D (7/97) - Environmental conditions and test procedures for airborne equipment: SECT 21 — Emissions of radio frequency energy (Radiated Emissions Only — Category M Limit)

UL2601-1 (1998) - Medical Electrical Equipment, Part 1: General requirements for safety

Specifications

General specifications (nominal)

Minimum increment of resolution:
0.005 Units per activation

Size:
3.2” × 1.8” × 0.95” (80mm × 47mm × 24mm)

Weight:
Approximately 3.2 ounces (90g) including battery and cartridge

Classification:
Type CF ♥ (protection from electric shock)

Moisture protection:
IPX8 (watertight to a depth of 12 feet [3.64 meters] for 3 minutes, or 8 feet [2.4 meters] for 30 minutes

Pump alarms/alerts:
Pump stopped, blockage, low battery, dead battery, low cartridge volume, empty cartridge, system fault, delivery limit
Optional alarms/alerts: end of temporary rate, temporary rate active, site change, check blood glucose, missed meal bolus, automatic off

Maximum infusion pressure:
23 psi

Maximum time to blockage (occlusion) alarm:

	Minimum	Maximum
Bolus 5 u/hr	24 sec.	48 sec.
2 u/hr	1 hr.	3.9 hrs.
0.05 u/hr	37 hrs.	74 hrs.

Bolus volume at blockage (occlusion) release:
Approximately 4 units

Power source:
One AAA (IEC LR03) alkaline battery.

☞ Caution: Do not use NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries. They will not power the pump properly, and the battery life indicator on the home screen may not show the correct amount.

Battery life:
The expected life of the battery is dependent upon the pump settings:
• Basal rate of 2 units/hour, vibratory alarm OFF, 5 boluses of 5 units per day: approximately 30 days
• Basal rate of 35 units/hour, vibratory alarm ON: approximately 4 days

Data storage time:
An internal battery powers the clock, and allows pump to store program parameters and history. The internal battery is charged by the AAA alkaline battery. Once fully charged (approximately 40 hours after AAA battery installed), the internal battery maintains pump programming and history for approximately 30 days. The life of the internal battery is 10 years minimum under normal use conditions.

Operating conditions:
Temperature: 2˚C to 40˚C (35.6˚F to 104˚F)
Humidity: 90% relative humidity (non-condensing) maximum
Atmospheric pressure: 70 kPa (or 10,000 feet above sea level) to 106 kPa (10.2 PSI to 15.4 PSI)

☞ Caution: Do not use the pump in hyperbaric chambers as they will affect how the pump works and may also cause damage to the pump.

Storage conditions:
Temperature: –20˚C to 60˚C (–4˚F to 140˚F)
Humidity: 90% relative humidity (non-condensing) maximum
Atmospheric pressure: 70 kPa (or 10,000 feet above sea level) to 106 kPa (10.2 PSI to 15.4 PSI)

Pushrod accuracy:
±1% linear travel

System delivery accuracy:
± 2% (nominal). At low delivery rates, this accuracy may not be achieved for short periods. During the total delivery time, the accuracy averages out.

System definition:
Deltec Cozmo™ Insulin Pump with Deltec Cozmo™ 3 ml Insulin Cartridge and a Deltec Cozmo™ Essential Infusion Set

Blockage (occlusion) alert:
18 psi ± 5psi

Bolus accuracy at set value of 0.1u:
± 15% (measurement error ± 10%)

Bolus accuracy at set value of 25u:
± 1.5% (measurement accuracy ± 0.5%)

Maximum volume infused under single fault condition:
Less than 2 units

Delivery rate during bolus:
Approximately 0.05 units per second minimum, 1.67 units per second maximum (based on bolus amount – all standard boluses to be delivered within 1 minute)

Delivery rate during Fill tubing/Fill cannula:
Approximately 1 unit per second

Basal Delivery Interval (minimum):
3 minutes (approximately 1/20 basal rate)

Delivery specifications

Main Menu

Meal Bolus:

User can program and deliver a meal bolus. If displayed, extended and combination bolus appear in menu. If displayed, any custom boluses appear in menu

Delivery Specifications:
Programming/delivering a bolus (Standard, Extended, and Combination):
Units - Insulin: 0 units to selected maximum bolus
Default: 0 units
Grams - Carb: 0 grams to selected maximum bolus × carb ratio
Default: 0 grams

Duration (Extended and Combination): 00:15 minutes to 8:00 hours in 00:15 minute increments
Default: 1:00 hour

Percent Immediate (Combination): 1% to 99% in 1% increments
Default: 50%

Setup in Pump Settings / Personalize / Delivery / Meal bolus menu
Type: Grams - Carb or Units - Insulin
Default: Units - Insulin

Maximum Bolus: 1.00 units to 25.00 units in 1.00 unit increments
Default: 15.00 units

Bolus increment: 0.05 units, 0.10 units, 0.50 units or 1.00 units

Default: 0.10 units

Carb ratio: 1u per 2grams to 1u per 50grams in increments of 1 gram

Default: 1u per 15grams

Carb increment: 1, 2, 3, 4, 5, 10 or 15 grams

Default: 5 grams

Display Extended bolus: Yes or No

Default: No

Display Combination bolus: Yes or No

Default: No

Allow Touch bolus: Yes or No

Default: Yes

Custom Bolus:

Review or edit; active boluses indicated by ☑ (up to 12 available, programmed using My Treatment Assistant™)

Edit (Display in menu): Yes or No. If using "grams of carbs" and answer is Yes, user selects carb ratio (see above)

Correction Bolus

If displayed, user can program and deliver a correction bolus

Delivery Specifications:

Current blood glucose:

mg/dl: 30 to 600 mg/dl in 1 mg/dl increments

Default: Target

mmol/L: 1.5 to 30.0 mmol/L in 0.1 mmol/L increments

Default: Target

Setup in Pump Settings / Personalize / Delivery / Correction Bolus menu

Display in Main Menu: Yes or No

Default: No

Display in Meal Bolus: Yes or No

Default: No

BG measured in: mg/dl or mmol/L

Default: mg/dl

Correction bolus - 1 unit decreases BG:

mg/dl: 5 to 200 mg/dl in the following increments:

- 1 to 30 mg/dl in increments of 1 mg/dl
- 30 to 100 mg/dl in increments of 5 mg/dl
- 100 to 200 mg/dl in increments of 10 mg/dl

Default: 50 mg/dl

mmol/L: 0.2 to 12 mmol/L in the following increments:
- 0.2 to 1.5 mmol/L in increments of 0.05 mmol/L
- 1.5 to 5 mmol/L in increments of 0.25 mmol/L
- 5 to 12 mmol/L in increments of 0.5 mmol/L

Default: 2.75 mmol/L

Duration of insulin action: 02:00 to 08:00 hours in 00:15 increments

Default: 03:00

Target blood glucose:
mg/dl: 80 to 150 mg/dl in 5 mg/dl increments

Default: 150 mg/dl

mmol/L: 4.4 to 8.3 mmol/L in 0.1 mmol/L increments

Default: 8.3 mmol/L

Temporary Rate

If displayed, user can program and deliver a temporary basal rate. If displayed, any custom temporary rates appear in menu

Delivery Specification:

Percent: 0% or 10% to 250% (or percentage that equals basal rate maximum) in 5% increments

Default: 100%

Units/hr: 0.00 units/hr or 0.05 to basal rate maximum in 0.05 units/hr increments

Default: current basal rate

Duration: 00:30 to 72:00 hours in 00:30 increments

Default: 00:30 minutes

Setup in Pump Settings / Personalize / Delivery / Temporary Rate menu

Temporary rate: Display in main menu: Yes or No

Default: No

Temporary rate method: Percent or Units/Hr

Default: Percent

Active alarm (Give alert while temporary rate is active): Yes or No

Default: Yes

If Yes, 00:15 to 02:00 hours in 00:15 increments

Default: 00:15 minutes

End alarm (Give alert when complete): Yes or No

Default: Yes

Custom Temporary Rates:
Review or edit; active temporary rates indicated by ☑ (up to 8 available, programmed using My Treatment Assistant™)
Edit (Display in menu): Yes or No

Basal Pattern

User can edit (4 patterns, each with a possible 48 time/rate segments) and start using basal patterns

Delivery Specifications:

Time: Midnight to 11:30PM in 00:30 increments or Midnight to 23:30 in 00:30 increments

Default: --:--

Rate: 0.00 u/hr (units/hour) or 0.05 u/hr to basal rate maximum

Default: 0.00 u/hr

Setup in Pump Settings / Personalize / Delivery / Basal Pattern menu

Number of patterns: 1 to 4 patterns may be displayed or not displayed

Default: 1 pattern displayed

Pattern names: Pattern "X" (1, 2, 3, 4), Exercise day, Weekday, Travel, Weekend, Monthly

Default: Pattern "X" (1, 2, 3, 4)

Basal rate maximum: 0.05 u/hr to 35.00 u/hr in 0.05 u/hr increments

Default: 2.00 u/hr

Load Cartridge

User loads cartridge, fills tubing, fills cannula, and selects site change alarm (if displayed)

Fill tubing: Fills in 1.0 unit increments until Stop is pressed (automatically stops at 30 units).

Fill cannula: 0.10 units to 1.0 units in 0.1 unit increments

Default: 0.0 units initially, then last programmed amount

Site change alert (if displayed - see Alert Specifications): 1 to 5 days in 1 day increments

Default: 3 days

12:30AM (00:30) to 11:30PM (23:30) in 00:30 minute increments

Default: 8:00 AM

History

User selects displayed report for viewing

View:

Memory:

Reports: last 90 days, arranged from most recent to oldest

Events: last 2000 events, arranged from most recent to oldest

Averages: User chooses number of days to average over: 2 to 30 days in 1 day increments

Default: 7 days

Pump Settings / Personalize / History

Display in menu:

Delivery summary: Yes or No

Default: No

Average delivery summary: Yes or No

Default: No

Basal as Percent of TDD (Total Daily Dose): Yes or No

Default: No

Avg basal as Percent of TDD: Yes or No

Default: No

Bolus history: Yes or No

Default: No

Complete history: Yes or No

Default: No

Pump Settings

Time and Date: Allows user to set time and date

Beep/Vibrate: Beep or Vibrate

Default: Beep

If beep, choose volume: Low, Medium or High

Default: High

Program Lock: Yes or No

Default: No

Pump Settings / Personalize / Alerts

Low cartridge volume: Alert at 5 units to 50 units in 1 unit increments

Default: 20 units

Delivery Limit: Alert at 1 unit to 100 units in 1 unit increments

Default: 40 units

Glucose Reminder: Yes or No

Default: No

If Yes, user chooses interval of 01:00 to 04:00 hours in 00:15 increments

Default: 02:00

Automatic off: Yes or No

Default: No

If Yes, user chooses interval of 01:00 to 24:00 hours in 01:00 increments

Default: 08:00

Display site reminder: Yes or No
Default: No

Missed Meal Bolus Alerts: User can program up to 4; active alerts indicated by ☑: Yes or No
Default: No

If Yes, user determines interval start and end time to monitor for bolus:
12:00AM (00:00) to 11:30PM (23:30) in 00:30 increments
Default: 12:00AM (00:00)

Regional Settings

Time Format: 12-hour or 24-hour
Default: 12-hour

Date Format: mm/dd/yy or dd/mm/yy
Default: mm/dd/yy

Number format: Decimal shown as Period or Comma
Default: Period

Personalization Using My Treatment Assistant™

Pump label: User can create name or other label on home screen pages

Home screen label: User can create personal information (e.g., clinic name/phone number, emergency contact name/phone number, etc.) on page 3 of home screen

Meal bolus: User can create up to 12 custom programs

Basal patterns: User can create name for basal patterns

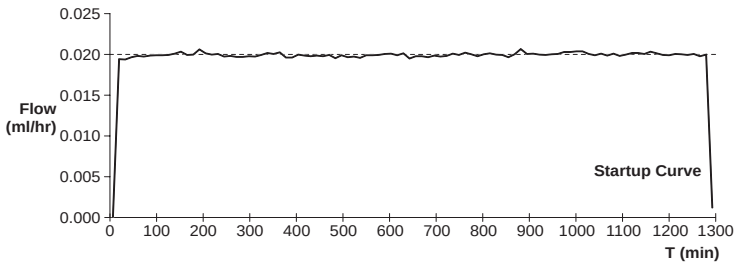
Temporary rate: User can create up to 8 custom programs

Accuracy test results

The following graphs are designed to show flow accuracy of the pump against given time periods. All graphs were plotted using a Deltec Cozmo™ 3mL Insulin Cartridge (21-1750) and Deltec Cozmo™ Essential Infusion Set (21-7200).

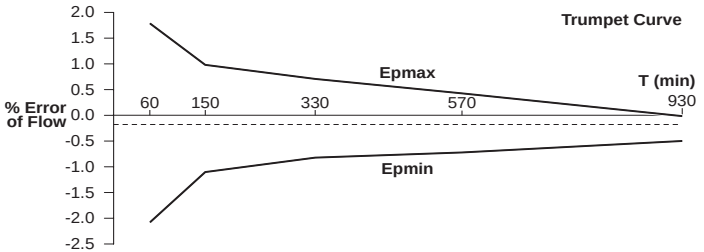
Flow rate from startup

Time interval:	15 minutes
Total time:	1455 minutes (24 hours, 25 minutes)
Programmed rate:	2.00 units/hr



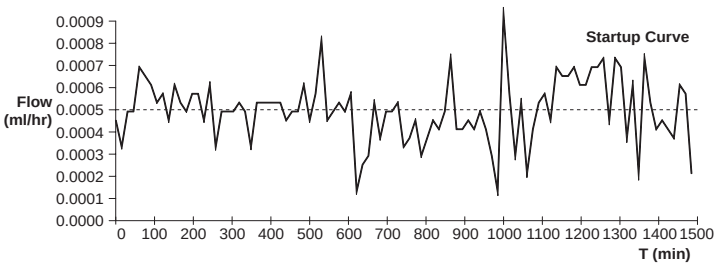
Flow rate error

Programmed rate:	2.00 units/hr
Average flow rate:	2.00 units/hr
Mean flow error:	0.18%



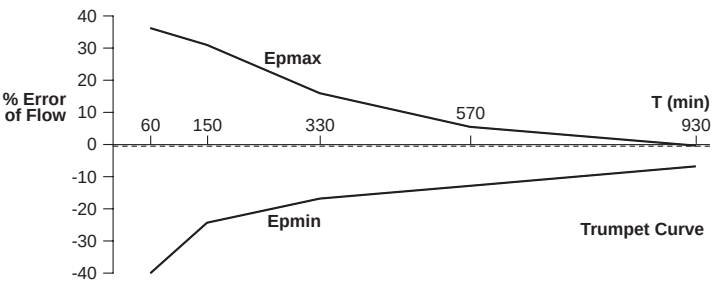
Flow rate from startup

Time interval:	15 minutes
Total time:	1485 minutes (24 hours, 45 minutes)
Programmed rate:	0.05 units/hr



Flow rate error

Programmed rate:	0.05 units/hr
Average flow rate:	0.05 units/hr
Mean flow error:	-00.67%



Safety features and fault detection

Hardware safety features

Key hardware safety features include a watchdog timer circuit, motor driver and motor watchdog circuits, and a voltage detector circuit. Each safety circuit performs a unique function to ensure the overall safety of the pump.

Watchdog timer circuit

The microprocessor must send an appropriate signal to the watchdog circuit at least once per minute. If the microprocessor does not send this signal, the circuit initiates a “time out” and shuts down the pump controller.

Watchdog timer circuitry is provided to monitor the status of the microprocessor, disable the motor, and cause the pump to beep if the microprocessor malfunctions. The microprocessor must “strobe” the watchdog circuit at least once per minute in order to prevent the watchdog from performing it's reset function. The microprocessor tests the watchdog circuit on every power up.

By setting a flag in the memory and not strobing the watchdog, the microprocessor can force a watchdog time out. After being reset, the microprocessor checks the status flag to see if this was a time out test. If it was, the microprocessor continues it's normal power up routine. If the reset occurred when the microprocessor was not expecting it, the microprocessor “traps” the event, an alarm is given (either beep or vibrate), and an error message appears in the display.

Motor drive/motor watchdog circuit

Motor drive circuitry is composed of a series of FET transistors, passive components, two voltage comparators and the second microprocessor. The second microprocessor times how long the motor runs each time it is turned on. If the motor runs for longer than the primary microprocessor specifies, the circuit times out and disables the motor. A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform the complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires. The software

verifies this function during the watchdog test described above.

Voltage detector circuit

Low voltage detection is performed by part of the watchdog circuit and by the microprocessor via software. 3 low voltage levels are detected. The first 2 levels are detected by software and the 3rd by hardware. The 1st level to be reached is the Low Battery Warning threshold, which occurs when the battery voltage decays to a point where less than 10% operating time is available. An Analog to Digital Converter (ADC) built into the microprocessor allows the microprocessor, via software, to monitor the battery voltage. At the Low Battery Warning threshold, the microprocessor enables an alarm (either beep or vibrate) and displays the low battery alert in the display. When the battery voltage drops to a point where it is too low to guarantee proper motor operation, the microprocessor via software stops delivery, generates an alarm (either beep or vibrate), and a depleted battery alarm message appears in the display. When the battery voltage drops to a value where operation of the microprocessor cannot be guaranteed, a hardware reset circuit is triggered which places the microprocessor in reset. This prevents ambiguous microprocessor operation as the battery voltage continues to decay. The hardware reset continues until the battery is completely depleted or it is removed. Once the pump controller goes into low battery shutdown, only replacing the depleted battery with a new battery will clear the condition.

Software safety features

Hardware-related software safety features

Program memory check

At power up and regular intervals thereafter, the program memory is tested by calculating a Cyclic Redundancy Code (CRC) on the program and then comparing it with the CRC stored with the program.

If the stored and calculated CRC do not match, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

RAM memory check

At power up, the Random Access Memory (RAM) is checked. A series of bit patterns is written to and read from each address in the RAM. If the read data is differ-

ent from the written data, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Motor circuit check

At power up and at regular intervals thereafter, the motor circuit is checked to ensure that no power is being applied to the motor unless the motor is actually on. If the software detects power being applied to the motor at any other time, it initiates an alarm (either beep or vibrate) and no longer attempts to deliver insulin. During every pump activation, the software checks to see whether the motor completes 1 activation. If the motor fails to turn, or fails to complete an activation, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Keypad encoder check

Every time the software receives data from the keypad, it is checked. If the data is not a valid keypress, the software disregards the keypress.

Data handling and software safety features

Data stored in RAM

Before use, data associated with delivery and stored in RAM is tested by calculating a CRC on the data and then comparing it with CRC stored in the data. If the stored and calculated data do not match, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Data stored in NOVRAM

Before use, data associated with delivery and stored in NOVRAM is tested by calculating a CRC on the data and then comparing it with CRC stored in the data. If the stored and calculated data do not match, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Data used in calculations

Calculations on data used in some way to control delivery of insulin are performed redundantly.

The 2 calculated values are then compared. If the 2 values do not match, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Timer data registers

The data in the Real Time Clock is checked at regular intervals. If the data is not reasonable, the software stops insulin delivery, initiates an alarm (either beep or vibrate) and a system fault alarm message appears in the display.

Inspecting the pump

Other than periodic visual inspection and cleaning of the pump, no testing of the pump is required. The pump's internal software, hardware and dual microprocessors are constantly checked while the pump is operating, and during the self tests performed during power up.

- Visually inspect the pump for any damage to the pump's outer shell. Look for chips or cracks. If the outer shell is chipped or cracked, the pump will no longer be watertight. Visually inspect the cartridge and battery chambers to make sure they are clean and free of foreign objects/materials.
- Visually inspect the display. If there are missing or incomplete characters, or if the display is otherwise damaged, stop using the pump immediately.
- Visually inspect the cartridge cap and battery cap. Make sure they fit properly and tightly on their respective compartments.

Reference the Cleaning your pump and Servicing your pump sections in chapter 4 if you need to clean or return your pump for service.

Index

A

Access site 9, 41, 69
Accessories 20
  belt clip 23
  cartridge 20
  infusion set 20
  IR adapter 20
Accuracy test results 114
Alarms 27, 55, 57
  Beep 27, 55
  troubleshooting 56
  Vibrate 27, 55
Alerts 28, 58
  automatic off 28, 58
  battery depleted 56
  blockage 56
  glucose reminder 2, 28, 35
  low cartridge 28
  missed meal bolus 28
  site reminder 28
  system fault 57
  troubleshooting 58
Aseptic Technique 2, 9, 35, 71
Automatic Off alarm 28, 58

B

Backlight 18, 55
Basal Rate 9
  & medication / supplements 74
  & your growth 74
  & your level of exercise 74
  & your monthly period 74
  & your weight 74
  maximum basal rate 50
Basal Rate Patterns 7, 49
  editing 51
  personalizing 50
  Temporary Basal Rates 8, 93
  using 53
Battery, AAA alkaline (IEC LR03) 4, 8, 16, 21
  Battery compartment 16, 21
Beep 27, 55
Belt clip 23
Blockage alert 56
Blood glucose (BG) levels 9
  mg/dl 12, 77
  mmol/L 12, 77
Bolus 10

C

Cannula 10
Carb ratio 11, 47
Cartridge 10, 20, 35
  filling 35
  loading into pump 36
Cartridge cap 16
Cell phones 4
Cleaning your pump 65
Combination bolus 8, 10, 89
  delivering 91
  display in menu 90
  stopping 92
Communications 102
Correction bolus 8, 77
  Correction bolus factor 10, 77
  delivering 80
  Duration of insulin action 10, 77
  mg/dl 12
  mmol/L 12
  personalizing 79
  Target blood glucose level 78
Correction bolus factor 10, 77

D

Data handling and software safety features 118
  data stored in NOVRAM 118
  data stored in RAM 118
  data used in calculations 119
  timer data registers 119
Date format 24
Dawn phenomenon 10
Delivering a correction bolus 80
Diabetic Ketoacidosis (DKA) 10, 70
  Ketones 11
Display 8, 16, 18
  backlight 18, 55
  screensaver 18
Duration of insulin action 10, 77

E

Editing Basal patterns 51
Emergency supplies 72
Extended bolus 8, 11, 85
  delivering 87

display in menu 86
stopping 88

F

Factor 11
Fill cannula 42
Fill tubing 40
Fluid path 9, 11

G

Gastroparesis 11
Glucose Reminder 2, 28, 35

H

History 9, 17, 99
reports 99
viewing 101
Home screen 18, 19
customizing 18
Hyperglycemia 3, 11, 41, 68
Hypoglycemia 2, 11, 35, 36, 67

I

Increment 11
Infusion set 20, 69
Infusion set tubing 2, 20
air in tubing 3, 41
Leaks at connectors 3, 41, 75
Inspecting and testing the pump 119
IR adapter 20
IR windows 16

L

Load Cartridge 1, 2, 35, 37
fill cannula 42
fill tubing 40
site reminder 28, 43
Lockout 9, 32
unlocking the pump 33
Low battery alert 59, 60, 61
Low cartridge 28

M

Magnetic Resonance Imaging (MRI) 4
Maximum basal rate 50
Meal Bolus 8, 44
Combination bolus 8, 10, 89
delivering 91
display in menu 90
stopping 92
Extended bolus 8, 11, 85
delivering 87
display in menu 86
stopping 88
maximum bolus 45, 47
personalizing 45, 47
Using grams of carbohydrate 8, 11, 44, 47
Increment 11, 47
Using units of insulin 8, 44, 45
Increment 11, 45
Menu 18, 19, 24
Basal Patterns 93
Correction Bolus 77
Delivery
Basal Patterns 50
Correction Bolus 79
Meal Bolus 45, 47, 86, 90
Temporary Rate 94
Load Cartridge 37
Meal Bolus 45
Personalize
Alerts 28
History 100
Regional Settings 24
Pump Settings 24
Beep/Vibrate 27
Lockout 32
Time and date 2, 24, 26
Temporary Rate 93
mg/dl 12, 77
mmol/L 12, 77
My Treatment Assistant™ PC Communications System 7, 18, 20, 44, 49, 93
IR windows 16

N

Number format 24

O

Occlusion 12, 17, 56

P

Pediatric Use 13
Programming keys 16
Pump development standards 105
Pump illustrations 15
Pump temperatures 73
Pushrod 12

R

Regional Settings 24
  date format 24
  number format 24
  time format 24
Restarting delivery 31

S

Safety features and fault detection 116
  hardware 116
  motor drive 116
  voltage detection 117
  watchdog 116
Safety Information 1
Screensaver 18
Self tests 22
Servicing your pump 66
Sick days 71
Site Reminder 28, 43
Skin infections 71
Software safety features 117
  hardware-related 117
  keypad encoder check 118
  motor circuit check 118
  RAM memory check 117
Specifications 106
  Delivery 108
  General 106
Sports 74
Subcutaneous 12
Suspending delivery 31
Symbols 6, 18
System fault alert 57

T

Target blood glucose level 78
Temporary Rate 8, 93
  personalizing 94
  stopping 96
  using 95
Time and date 2, 24, 26
Time format 24
Time-out 18
Touch bolus 16, 44, 81, 83
  allow feature 82
  delivering 83
  Touch bolus button 16, 81
Troubleshooting 56, 67
  access site problems 69
  alarms 56
  alerts 58
  health problems 67
    diabetic ketoacidosis (DKA) 70
    hyperglycemia 68
    hypoglycemia 67
    sick days 71
    skin infections 71
  infusion set problems 69

U

Unlocking the pump 33
Up and Down keys 16, 18
Using Basal patterns 53

V

Vibrate 17, 27, 55

W

Watertight 8, 17, 73

Limited Warranty

Deltec, Inc. (the "Manufacturer") warrants to the Original end-user Purchaser that the Deltec Cozmo™ Insulin Pump (the "Pump"), excluding accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this User's Manual, for a period of four (4) years from the date of purchase by the Original end-user Purchaser. This warranty does not cover normal wear and tear or maintenance and specifically excludes all accessories, including, but not limited to batteries, infusion sets, cartridges, apparel, equipment, computers and printers used with the Pump.

Limitation of Remedies

The Manufacturer will replace without charge (except for postage and handling) any Pump (excluding all accessories) which is determined by the Manufacturer to be defective during the four (4) year warranty period. The replacement Pump which the Original end-user Purchaser receives under this warranty may be a refurbished Pump. If the Original Purchaser requires that the original Pump be repaired and returned, this must be requested to the Manufacturer at the time of reporting the warranty defect. In the event the Pump is replaced or repaired, the warranty period will not extend beyond the original warranty period. THIS IS THE EXCLUSIVE REMEDY.

Parties Covered:

This Warranty extends only to the Original end-user Purchaser of the Pump. This Limited Warranty does not extend to subsequent purchasers. The Original end-user Purchaser should retain the invoice or sales receipt as proof of the actual date of purchase by the Original end-user Purchaser.

Conditions of Warranty:

This warranty is valid only if the Pump is used in accordance with this User's Manual. The warranty will be void in the following cases:

1. The Pump has been altered, misused (misuse includes, but is not limited to use not in accordance with this User's Manual, used with accessories not approved by the Manufacturer and/or used with a computer program other than that licensed by the Manufacturer) or damaged by neglect or accident;
2. The Pump has not been properly maintained or repaired by persons not authorized by the Manufacturer; or
3. The Pump serial number has been removed or damaged.

Exclusions:

All other warranties, express or implied, are excluded, including but not limited to the warranties of merchantability and fitness for a particular purpose or use. The remedies provided in this Warranty are the exclusive remedies available to the Original end-user Purchaser for any breach of this Warranty and no person has the authority to bind the Manufacturer to any representation, condition or warranty except this Warranty.

The Pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Pump for a particular medical treatment and patient.

The Manufacturer, its distributors nor suppliers shall not be respon-

sible for any incidental, special or consequential damages of any kind or nature caused by or arising out of a defect or malfunction of the Pump.

Warranty Procedure

Notice of the claimed warranty defect must be made in writing, fax or by telephone to the Manufacturer as follows: Attention: Deltec, Inc., 3183 Riverport Tech Center, Maryland Heights, MO 63043 U.S.A. Telephone: 1.800.826.9703. Facsimile: 1.800.209.2145 or if outside the USA contact your local distributor. Original end-user Purchaser must include date of purchase by the Original end-user Purchaser, model and serial number, and a description of the claimed warranty defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary.

AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PUMP. If authorized, the Pump must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

This Warranty gives the Original end-user Purchaser specific legal rights. The Original end-user Purchaser may have other legal rights which may vary from state to state.

Deltec

Deltec, Inc.
St. Paul, Minnesota 55112 USA
www.DeltecCozmo.com
Customer Service (USA, Canada): 1-800-826-9703
Fax: 1-800-209-2145

European Representative:

Graseby Medical Ltd.
WD24 4LG, UK
Tel. +44 (0)1923 246434

CE 0473

Deltec Cozmo, Deltec Cozmo logo design, The Freedom to Be You and My Treatment Assistant are Deltec, Inc. trademarks.

Microsoft® and Microsoft® Windows® are trademarks of Microsoft Corporation. I.V. Prep® is a registered trademark of Zeneca Pharmaceuticals, a business unit of Zeneca Inc. Hibiclens® is a registered trademark of Smith & Nephew. Betadine® is a registered trademark of Purdue Fredericks Company. Q-Tip® is a registered trademark of Johnson & Johnson. Formula 409® is a registered trademark of Clorox Co. GooGone® is a registered trademark of Magic American. Deepwoods Off® is a registered trademark of SC Johnson Company.

U.S. and foreign Patent(s) pending.

© 2002 Deltec, Inc.
All rights reserved. Printed in USA.
2002-11 40-5118-51A

smiths
Smiths Medical – a part of Smiths Group plc